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PTO/SB/16 (5-03)

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Richard S.	Stack	106 Alder Place, Chapel Hill, North Carolina 27514
Dan	Balbierz	973 Cambridge Road, Redwood City, California 94061
John	Lunsford	123 Leslie Drive, San Carlos, California 94070
Kevin	van Bladel	1425 Murdell Lane, Livermore, California 94550

☒ Additional inventors are being named on the 1 separately numbered sheets attached hereto
TITLE OF THE INVENTION (280 characters max)**DEVICES AND METHODS FOR RETAINING A GASTRO-ESOPHAGEAL IMPLANT**

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☒ Firm or Individual Name **STALLMAN & POLLOCK LLP**
Address **Attn: Kathleen A. Frost**Address **121 Spear Street, Suite 290**City **San Francisco** State **CA** ZIP **94105**Country **U.S.A.** Telephone **(415) 512-1312** Fax **(415) 512-1362****ENCLOSED APPLICATION PARTS (check all that apply)**
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☒ Drawing(s) Number of Sheets 17
☐ Other (specify)
☐ Application Data Sheet. See 37 CFR 1.76
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)
☒ Applicant claims small entity status. See 37 CFR 1.27.

☒ A check or money order is enclosed to cover the filing fees

☒ The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number 50-1703
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are:

Respectfully submitted,

SIGNATURE

Kathleen A. Frost

Date

10/10/2003TYPED or PRINTED NAME **Kathleen A. Frost**

REGISTRATION NO.

37,326

(if appropriate)

Docket Number.

BARO-700TELEPHONE **(415) 512-1312****USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT**

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INVENTOR(S)/APPLICANT(S)			
Given Name (first and middle [if any])	Family or Surname	Residence (City and either State or Foreign Country)	
William S. William L. Richard A.	Eubanks Athas Glenn	3010 Quincemoor Road, Durham, North Carolina 27712 3901 King Charles Road, Durham, North Carolina 27707 308 Westside Drive, Chapel Hill, North Carolina 27516	

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CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)Applicant(s): **Richard S. Stack et al.**

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Provisional Application for Patent Cover Sheet (including 19-page provisional patent application and 17 sheets of informal drawings)*(Identify type of correspondence)*

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

October 10, 2003*(Date)*Georgia K. Stith*(Typed or Printed Name of Person Mailing Correspondence)**(Signature of Person Mailing Correspondence)*EV338307054US*("Express Mail" Mailing Label Number)***Note: Each paper must have its own certificate of mailing.**

DEVICES AND METHODS FOR
RETAINING A GASTRO-ESOPHAGEAL IMPLANT

5 **Inventors:** Richard S. Stack, MD; Dan Balbierz; John Lunsford; Kevin van Bladel;
William S. Eubanks MD, William L. Athas, Richard A. Glenn

Field of the Invention

The present invention relates generally to the field of gastro-esophageal implant
10 devices, and specifically to devices and methods for retaining such implants within the
gastro-esophageal junction region of a patient.

Background of the Invention

An anatomical view of a human stomach S and associated features is shown in Fig. 1.
15 The esophagus E delivers food from the mouth to the proximal portion of the stomach S.
The z-line or gastro-esophageal junction Z is the irregularly-shaped border between the thin
tissue of the esophagus and the thicker tissue of the stomach wall. The gastro-esophageal
junction region G is the region encompassing the distal portion of the esophagus E, the z-
line, and the proximal portion of the stomach S.

20 Stomach S includes a fundus F at its proximal end and an antrum A at its distal end.
Antrum A feeds into the pylorus P which attaches to the duodenum D, the proximal region of
the small intestine. Within the pylorus P is a sphincter that prevents backflow of food from
the duodenum D into the stomach. The middle region of the small intestine, positioned
distally of the duodenum D, is the jejunum J.

25 Prosthetic devices for use in controlling obesity are shown and described in U.S.
Application No. 09/940,110, filed August 27, 2001 and U.S. Application No. 10/118,289
filed April 8, 2002, and U.S. Provisional Application No. 60/379,306 filed May 10, 2002,
U.S. Application No. 10/345,666, filed January 16, 2003. These applications are owned by
the assignee of the present application, and the disclosures of these applications are
30 incorporated herein by reference. Certain forms of these devices involve positioning a
restrictive device such as a prosthetic pouch of the type shown in Fig. 2A in the proximal

stomach as shown in Fig. 2B. The pouch 2 includes a proximal opening 4 and a smaller distal opening 6 and forms a small reservoir that collects masticated food from the esophagus – thereby limiting the amount of food that can be consumed at one time. Because of its small volume (which may be on the order of approximately 2 cc-300cc in volume, but is preferably in the range of 10-30 cc), the pouch functions to limit the amount of food that can be consumed at one time. Over time the food within this reservoir descends into the stomach through the exit port.

As the pouch fills with food, it may distend, imparting pressure against the upper stomach and lower esophageal sphincter causing the patient to experience sensations of fullness. The pouch may additionally or alternatively act as a restrictor, limiting the amount of food intake.

The pouch 2 may be formed of a flexible material that will prevent passage of food through the sides of the pouch. Examples of such materials include, but are not limited to polyesters (e.g. Dacron® polyester), ePTFE fabric (e.g. GoreTex® fabric or others), a polyurethane such as ChronoFlex® polyurethane, nylon fabrics, silicone, other polymeric materials, and bio-absorbable materials (e.g. PLLA, PGA, PCL, poly-amhydride etc). The material may be a composite of compliant, semi-compliant and/or non-compliant materials that give different regions of the pouch different degrees of compliance so as to allow/limit expansion of the pouch in various locations. For example, it may be desirable to provide the pouch with a fairly elastic exit port to as to prevent occlusion in the event a large piece of food is ingested and/or to control the exit pressure of food from the pouch, whereas the proximal end of the pouch may be stiffer to prevent bulging. Varying degrees of compliance may also be built into the pouch by varying the cross-sectional thickness in different regions of the pouch. The material may be coated with a lubricious, bio-compatible, chemically inert material, such as paraflex, to reduce friction on the base material's surface which will help prevent sticking and food build up on the device.

The flexible pouch material may be reinforced with, constructed of, or supported by supporting members, such as a soft mesh, a cage structure, ribs, rings etc. The supporting members may be formed of stainless steel, polymer, shape memory materials such as nitinol, shape memory alloys, or shape memory polymers, or thickened regions of material. The

pouch may be constructed so as to be self-expanding, such that the pouch springs radially open into an expanded condition upon ejection from a deployment device or catheter.

The pouch may be fixed in place using sutures 8a, 8b or other means such as clips, suitable adhesives at anchor points around the perimeter of the proximal opening 4. The
5 pouch 2 may include a reinforced rim section 9 for receiving the sutures 8a, 8b or other anchoring means. As illustrated in Fig. 2B, where anchoring means such as clips or sutures are used, the anchoring means may be passed completely through the wall of the stomach as with suture 8a (called a "full thickness" suture or clip), or partially through the wall of the stomach as with suture 8b (called a "partial thickness" suture or clip). One suture attachment
10 device found useful for applying sutures between the pouch and tissue is the "Sew-Right" suturing device available from LSI Solutions of Victor, New York,. Although the pouch may be secured to the esophageal tissue, it is more preferable to apply sutures/clips below the Z-line to allow for attachment to the thicker tissue of the stomach wall.

Once secured within the stomach, the implant and associated anchoring means are
15 subjected to significant forces caused by stomach motility and by forces imparted against the pouch by ingested food. Similar forces may be subjected to other forms of gastro-esophageal implants, such as prosthetic valves implanted within the esophagus for treatment of gastro-esophageal reflux disease. Over time, such forces could cause the implant to become detached from the wall of the stomach or esophagus due to erosion of the
20 stomach/esophageal tissue at the anchoring points. It is thus desirable to provide an anchoring mechanism that will retain an implant within the stomach and/or esophagus over an extended period of time.

Brief Description of the Drawings

Fig. 1 is a schematic illustration of a human stomach and a portion of the small intestine.

Fig. 2A is a perspective view of a restrictive device of a type that may be used to promote weight loss.

Fig. 2B is a cross-sectional elevation view of an esophagus and proximal stomach, showing the restrictive device of Fig. 2A implanted in the gastro-esophageal junction region.

Fig. 3A is a schematic illustration of a portion of an exterior stomach wall, showing a pledget anchored to the wall as an external reinforcement to a internally positioned restrictive device.

Fig. 3B is a schematic illustration similar to Fig. 3A, showing a T-bar anchored to the wall as an external reinforcement to an internally positioned restrictive device.

Fig. 4A is a schematic illustration of the exterior of a lower esophagus and proximal stomach, showing "moly bolt" type external reinforcements used to facilitate anchoring of an internally positioned restrictive device. Figs. 4B and 4C are cross-sectional side views showing introduction of the external reinforcement device through the stomach wall and its subsequent expansion to anchor a restrictive device in place

Figs. 5A through 5C are schematic illustrations of the exteriors of a lower esophagus and proximal stomach, each showing four additional embodiments of external reinforcements used to facilitate anchoring of an internally positioned restrictive device.

Fig. 6A is a perspective view of a stud-type fastener which may be used to connect an internally positioned restrictive device to an external reinforcement device. Figs. 6B through 6F are side elevation views showing examples of means for connecting the device of Fig. 6A through stomach tissue to the externally positioned external reinforcement device. The stomach tissue is shown in cross-section.

Figs. 7A and 7B are cross-sectional side elevation views showing self-balancing external reinforcements connected to stomach tissue. Fig. 7A shows the reinforcements in an equilibrium state, whereas Fig. 7B shows the alteration of the reinforcements in response to a force.

Figs. 8A through 8I are schematic illustrations of a lower esophagus and proximal stomach, each showing a different embodiment of an external collar.

Fig. 9A is a cross-sectional side elevation view of a distal esophagus, proximal stomach, and external collar.

Fig. 9B is a perspective view of the collar shown in Fig. 9A in a straightened configuration.

Fig. 9C is a perspective view of a collar of the type shown in Fig. 9B, but having an alternative locking mechanism.

Figs. 10 -12 are cross-sectional plan views of a portion of a stomach and esophagus, showing restrictive devices and arrangements of components for retaining the restrictive devices in position.

5 Fig. 13A is a top perspective view looking down into a stomach and illustrating the use of plications for retaining a ring within the stomach.

Fig. 13B is a cross-section view of a plication and ring taken along the plane designated 13B-13B in Fig. 13A.

Fig. 13C is a top perspective view similar to Fig. 13A illustrating the use of plications for retaining an alternative ring within the stomach.

10 Fig. 13D is a top perspective view looking down into a stomach and illustrating the use of plications for retaining multiple members within the stomach.

Fig. 14A is a cross-sectional top view of a stomach, illustrating plications formed in the stomach. Fig. 14B is a cross-sectional elevation view of a plication illustrating use of the plications to support a liner within the stomach.

15 Figs. 15A and 15B are a cross-sectional side view of a stomach wall illustrating methods for forming plications in the stomach wall.

Fig. 16A is a front perspective view of a stomach wall illustrating formation of a vertical plication in the wall.

20 Fig. 16B is a perspective view of an implant which may be supported by vertical plications of the type shown in Fig. 16A.

Fig. 16C is a perspective view looking downwardly into the interior of a stomach, illustrating placement of the implant of Fig. 16B into tunnels formed by plications of the type shown in Fig. 16A.

25 Fig. 16D is a front schematic illustration of an esophagus and stomach, illustrating formation of plications using a surgical stapler.

Fig. 16E is a cross-section view of a plication, taken along the plane designated 16E-16E in Fig. 16D.

30 Fig. 16F is schematic illustration similar to the illustration of Fig. 16D, but showing the stomach and esophagus in cross-section and further showing an implant being retained by the plications.

Fig. 16G is a cross-section view of a portion of a stomach wall, showing a modification to the Fig. 16D-16F arrangement in which the plication is formed from within the stomach.

5 Figs. 17A –19 are cross-sectional front views of an esophagus and stomach illustrating the use of rings to retain an implant.

Fig. 20 is a cross-sectional front view of a proximal stomach illustrating a method of forming an anchoring structure within the stomach.

Fig. 21A is a perspective view of a first example of an alternative to the restrictive device of Fig. 2A, in which the restrictive device takes the form of a rigid ring.

10 Fig. 21B is a perspective view of a second example of an alternative restrictive device, which has a tapered geometry.

Fig. 21C is a perspective view of a third example of an alternative restrictive device, which has a bellows configuration.

15 Fig. 21D is a perspective view of a fourth example of an alternative restrictive device, which includes a collection of separate segments that collectively form a restriction in the stomach.

Detailed Description of the Drawings

20 The drawings show a number of methods and components that may be used individually or in combination with one another to facilitate retention of an implant in the stomach, esophagus, or gastro-esophageal junction region. These methods and components may facilitate retention by (1) modifying the structure of the tissue at the implant location in a manner which allows the tissue to aid in retaining the implant either with or without a physical connection between the tissue and the implant; (2) anchoring the devices in place;

25 and/or (3) facilitating even distribution of forces (e.g. due to food pressure or stomach motility) around the implant to minimize the change of tissue erosion at points where the implant is anchored to tissue. Other ones of the described components are alternative embodiments to the restrictive device 2 of Fig. 2 which have features that may facilitate retention or even distribution of forces.

30 For the purposes of this application, the terms “restrictive devices”, “satiation devices” or “satiation pouches” will be used to mean devices or pouches intended to induce

weight loss in one or more of a variety of ways. These include, but are not limited to, physically restricting the amount of food that can be consumed, and/or imparting pressure against portions of the body (e.g. stomach, esophagus, esophageal sphincter, etc) causing the patient to experience sensations of fullness, and/or affecting levels of hormones or other substances in the body that control or affect feelings of hunger, and/or affecting the amount of ingested food absorbed by the body. The anchoring devices and methods described herein are useful for various types of satiation implants, including those not specifically described herein and including those positionable in the esophagus, the gastro-esophageal junction region and other portions of the stomach including the proximal stomach, fundus, antrum, etc.

It should be noted, however, that although the embodiments are described in the context of satiation devices, the components and methods described for facilitating retention and/or distribution of forces may be equally suitable with other types of implants, such as prosthetic valves for the treatment of gastro-esophageal reflux disease. The term "implant" will be used to refer to satiation devices as well as other types of medical devices that may be implanted in the esophagus, gastro-esophageal junction, and/or stomach.

External Reinforcements

Several components described in this disclosure function as external reinforcement devices. As discussed in Fig. 2B, the implant such as pouch 2 may be sutured or clipped into place by passing a full thickness suture 8a from the pouch 2 through the adjacent stomach tissue and back to the pouch. However, in some patients it may be desirable to "buttress" the sutures 8a by passing them through an external reinforcement device positioned on the exterior surface of the wall. Examples of external reinforcement devices include pledgets (Fig. 3A) or t-bars 12 (Fig. 3B), each of which distributes forces imparted against the suture over a larger surface area. Pledgets or t-bars may be quite large (e.g. 10 - 30 mm in diameter) or fairly small (e.g. 1 - 2 mm in diameter) as dictated by the particular application. Examples of material suitable for the pledgets or t-bars include silicone, felt, and/or the materials listed above for use in constructing the pouch. T-bars may also be formed of metallic bars crimped onto suture ends.

During implantation of the pledgets 10, the implant such as pouch 2 (Fig. 2A) may be introduced into the stomach endoscopically, while the pledgets are placed in contact with the

exterior of the stomach a laparoscopic or surgical approach. Sutures are passed from within the stomach, through the stomach wall, through the pledgets, and back to the interior of the stomach. If desired, this may be carried out in two procedures: for example a first laparoscopic procedure in which pledgets are laparoscopically sewn onto the exterior wall of the stomach, and a second endoscopic procedure in which the implant is passed through the esophagus and into the stomach and in which sutures are passed between the implant, stomach wall, and pledgets.

During implantation of the t-bars, the end of the suture having the t-bar attached to it is endoscopically positioned adjacent the exterior wall of the stomach, and the free end is sewn through the stomach wall and the internally positioned implant wall.

Fig. 4A shows an alternative external reinforcement device which takes the form of a "moly bolt" type fasteners 14 that may be introduced endoscopically through the esophagus into the stomach. Referring to Fig. 4B, during implantation, the implant (e.g. pouch 2) is positioned against the stomach and fasteners 14 are passed from the interior of the implant through the implant wall and through the stomach wall. Each fastener 14 includes an internal wire or string (not shown) that is attached to its distal portion 16. The distal portions 16 of the fasteners 14 are expanded into the position shown in Fig. 4C by pulling on these wires or strings, thereby anchoring the fasteners 14 in place.

Other types of external reinforcement devices are shown in Figs. 5A through 5C. In the Fig. 5A embodiment, inflatable balloons 18 may be passed through the implant and stomach wall from the stomach interior (in similar fashion to that shown in Fig. 4B for the moly bolt type fasteners), and then subsequently inflated such that the expanded balloons remain on the exterior surface of the stomach.

Figs. 5B and 5C illustrate alternatives to the pledgets 10 described with respect to Fig. 3A. As with the Fig. 3A pledget, the pledgets of Figs. 5B and 5C are positioned on the exterior wall of the stomach and sutures are passed through the pledgets to attach the implant to the stomach wall. As shown in Fig. 5B, the pledgets 10a may have roughened surfaces to prevent them from slipping through the suture openings in the stomach wall. Fig. 5C illustrates that pledgets 10b may be formed of mesh or other material known to promote cell ingrowth, such that over time the stomach wall tissue will grow into the pledget to enhance anchoring.

As another alternative to the pledget 10, a pledget may be formed in situ by injecting a drop of gel onto the exterior surface of the stomach, where the gel is a type that will solidify on the tissue surface. The gel may be delivered laparoscopically by approaching the stomach wall from outside the stomach, or it may be delivered endoscopically by injecting the gel using a needle passed through the wall of stomach from the stomach interior. Once the gel hardens into a pledget, the implant may be anchored to the hardened gel pledget using sutures, clips, etc. passed through the stomach wall. As yet another alternative, the gel may be injected in between the serosal and mucosal layers of stomach wall tissue to form the gel pledget within the stomach wall.

Naturally, each of the external reinforcement devices described above must in some way be connected to the implant located in the interior of the stomach. Fig. 6A shows a "stud" type fastener 20 of a type that may be attached to a implant within the stomach, and that is also connected to an external reinforcement device (not shown in Fig. 6A). Fastener 20 includes a first button 22 having a pin 24, and second button 26 having a bore for receiving the pin 24. As shown in Fig. 6B, pin 24 is passed through the wall of the implant (e.g. pouch 2) such that one of the buttons 22 is on the exterior of the implant and the other button 26 is on the exterior of the pouch. Fastener 20 is then connected to an external reinforcement device such as a pledget 10 positioned on the exterior wall of the stomach as shown.

As shown in Figs. 6B through 8F, various devices may be used to connect the fastener 20 to the pledget 10. It should be noted that although the implant is only shown in Fig. 6B, it should be assumed that in Figs. 6C through 6F implant is attached to the fastener such as in the manner shown in Fig. 6B.

Referring to Fig. 6B, a suture 28 may be sewn through the stomach wall and attached to both the fastener 20 and the pledget 10 using suitable means. For example, to secure the suture 28 to the fastener 20, the suture may be tied to the pin 24, or it may be threaded through an opening in the button 22 and into a bore in the pin 24, and the pin 24 may be crimped down to secure the suture within it. A variety of types of sutures may be used for this purpose, for example monofilament, braided suture, cotton, silk, or bioabsorbable suture.

The length of suture between the fastener 20 and pledget 10 may be highly tensioned or loosely tensioned. Referring to Fig. 6C, if it is desirable to keep the suture in tension, the

pledget 10 and fastener 20 may be magnetized to the same polarities such that they will resist movement towards one another as indicated by arrows and to thus maintain the tension of the suture. Alternatively, as shown in Fig. 6D the pledget 10 and fastener 20 may be magnetized to opposite polarities such that the attraction between them holds both the pledget, implant, and fastener against the stomach tissue. This embodiment may utilize a rigid post 30 (e.g. stainless steel, nitinol, plastic) extending between the pledget 10 and fastener 20 to protect the tissue from being compressed between the pledget 10 and fastener 20. As another alternative, the rigid post 30 may provide the connection between the pledget 10 and fastener 20, without the use of magnetism. As shown in Figs. 6E and 6F, a physical connector between the pledget 10 and fastener 20 may be formed of a material that promotes tissue ingrowth, such as a chain 31a or mesh 31b formed of nitinol, stainless steel, polymer, or bio-absorbable material.

Referring to Fig. 7A, external reinforcement may alternatively be provided by a combination of self-balancing anchors. This may take the form of a pair of balloon pledgets 32a, 32b connected by a suture 28 extending through the stomach wall such that one balloon 32a is within the stomach and the other balloon 32b is outside the stomach. The suture preferably extends through the interior of each balloon and is attached to the balloon at a point that is furthest from the adjacent stomach wall. The implant (not shown) is connected to the suture adjacent to the balloon 32a positioned within the stomach. As illustrated in Fig. 7B, the balloons are proportioned such that when force draws one of the balloons 32a away from the stomach wall (such as when the implant pulls inwardly in response to food pressure) the other balloon compresses and flattens against the wall, thereby increasing the effective pledget size and thus distributing the force over a larger area. It should be noted that the balloon pledgets could be replaced with other resilient structures such as three-dimensional mesh, stent-like frame structures, deformable elastomers, or other structures that will deform when subjected to force but that will resume their original shape upon release of the force.

Collars

Another form of external reinforcement device is an external collar encircling the exterior of the stomach. Figs. 8A through 8I show a variety of collar configurations. Some of these configurations are intended to be physically connected to the implant using sutures or

other connection methods, including those shown in Figs. 6B – 6F for connecting the implant to the pledget-type devices. These connections may be made with or without the stud fasteners of Fig. 6A. When connected to the implant, the collars may function like the pledgets 10 to facilitate even distribution of forces around the implant. The collars and
5 pledgets may also be combined such that a collar encircles the exterior stomach wall and pledgets on the exterior surface of the collar are connected to the device using sutures passed through the collar and the stomach wall. In this configuration, the collar aids in force distribution and also prevents the pledgets from eroding the stomach wall.

For other configurations, the collar is not physically connected to the implant, but
10 may be positioned to restrict movement of the device.

The collar embodiments of Fig. 8A through 8F are designed to have the implant device anchored to them at anchor points 38. The collars are intended to be flexible so as to more evenly distribute forces rather than to have significant forces build at any one anchor point. In the Fig. 8A embodiment, the flexibility of the collar 36 comes from its pleated
15 structure. The implant 2 within the stomach is attached to the collar at 36 anchoring points 38. The Fig. 8B collar 40 is formed of a coil spring. In both of these embodiments, the flexibility of the collar allows the anchoring points 38 to move with the stomach rather than allowing forces at the anchor points to build when such stomach movement occurs.

Similar properties are found in the Fig. 8C – 8E embodiments. In the Fig. 8C
20 embodiment, the collar 44 is formed of material such as stainless steel, polymeric, or nitinol mesh that has flexibility in multiple directions. The Fig. 8E collar 48 is also capable of stretching in multiple direction due to its use of a thin flexible polymeric sheet. In the Fig. 8F embodiment, the collar 50 includes a plurality of individual pledgets 52 mounted to an elastic member 54. Fig. 8D shows an expandable collar 53 formed of telescoping
25 components 55a, 55b. Spring members 57 connect the components 55a, allowing the collar to expand and contract with the stomach.

Referring to Figs. 8G, 8H and 8I, the collar may be a simple round or oval-shaped ring. It may have a torroidal shape like the collar 56 of Fig. 8G, or a tapered shape like the
30 collar 58 of Fig. 8H which conforms to the tapered shape of the exterior stomach wall. The collar may be rigid or flexible. Alternatively, referring to Fig. 8I, collar 60 may be flexible

but include a tensioning cable that may be activated to increase the rigidity of the collar. With these embodiments, sutures attached to the implant may be sewn through the stomach wall and be attached to the collar, or the collar may remain physically separate from the implant but function to maintain the implant's position as discussed in greater detail in connection with Fig. 10.

Fig. 9A shows a front cross-section view of the collar 56 surrounding an exterior stomach wall. As shown, collar 56 may have a D-shaped cross-section to minimize tissue trauma.

Because the collar is intended to be wrapped around the stomach, its design must be such that it can be introduced into the stomach cavity in an elongate configuration, and then have its free ends attached to form it into a loop around the stomach. As illustrated in Fig. 9B, collar 56 may include a slot 62 at one end and a tab 64 at the opposite end. Tab 64 is engageable within the slot to form the collar in to a loop. Raised buttons 66 on the tab 64 may snap into recesses 68 in the slot to lock the collar in the closed loop. The size of the collar may be pre-selected by cutting the tab 64 to the desired length before it is inserted into the slot.

As an alternative shown in Fig. 9C, collar 56 may include a sleeve 70 that is slidable over the collar as indicated by arrows to retain the ends of the collar 56 together once the collar has been positioned around the stomach.

Retention Methods

Numerous devices for anchoring the implant within the stomach have been described above. As discussed, many of those devices and associated methods may be combined if desired. Figs. 10 - 19 illustrate various other methods for retaining an implant within the stomach, some of which involve physically connecting the implants to body tissue and others which completely or largely avoid the use of physical connections between the implants and the body tissue.

In some of these embodiments, a portion of the implant is captured within a tissue structure formed within the body. As will be appreciated from the description that follows, such tissue structures may be strictures created in the stomach to retain the device, or they may be tunnels or ledges formed by creating plications in the stomach tissue.

The configuration shown in Fig. 10 is advantageous in that it can be used without sutures or other physical attachments between the implant or body tissue, although it can also be used with partial thickness sutures or anchors (which only go through a portion of the wall thickness) or "full thickness" sutures or anchors that penetrate through the full thickness of the wall of the gastro-esophageal junction, esophagus, or stomach.

Referring to Fig. 10, components positionable within the stomach include a hourglass shaped liner 80 having a waist section 82, and an implant such as pouch 2 positioned within the liner 80. Preferably, the contour of the liner 80 silhouettes that of the proximal portion of the pouch 2 as shown. The liner 80 is sufficiently rigid to restrict movement of the pouch 2 up or down within the stomach.

A ring 81 is positioned on the exterior surface of the body wall surrounding the waist portion 82 of the hourglass liner 80, such that it causes the body wall tissue to conform to the hourglass shape of the liner 80, altering the shape of the stomach by creating a stricture as shown. If necessary, the ring 81 may be secured in place using partial or full thickness sutures, barbs, clips etc. The ring 81 may have features similar to the collar 56 described in connection with Fig. 8G.

The relative positions of the ring 81, liner 80 and pouch 2 are such that the ring holds the liner 80 in position, and the liner in turn holds pouch 2 in position. Optional mounting studs 20 may be connected to the pouch 2 and sutured through the liner 80 to the body wall using partial or full thickness sutures. The liner 80 protects the mucosal lining of the stomach against erosion, and both the liner 80 and the ring 81 are themselves sufficiently flexible to prevent/minimize tissue erosion caused by their own surfaces.

An optional feature in the Fig. 10 configuration include a fundal component 84 extending in a distal direction from the liner 80. The fundal component 84 functions to reduce the area of the fundus exposed to ingested food. Over time, the presence of the fundal component may cause cells within the stomach to decrease their production of Ghrelin, the hormone that causes feelings of hunger. Thus, the overall level of hunger experienced by a patient will decrease and may result in weight loss by the patient. Contact between the fundal component and surrounding tissue may additionally aid in weight loss by causing the patient to experience sensations of fullness.

Another optional feature in the Fig. 10 configuration includes a proximal chute 86 which extends the pouch 2 into the esophagus. This restricts dilatation of the stomach in the region above the ring 81 and thus provides additional restriction against overeating by the patient.

5 Another configuration shown in Fig. 11 is similar to the Fig. 10 configuration, but it adds sutures 87 extending between tissue above and below the ring 81 to form plications 88 in the tissue to retain the ring in place. The plications 88 are formed by grasping tissue above and below the ring, and then suturing the grasped bunches of tissue together (see Figs. 15A and 15B and associated discussion). Obviously, in this and each of the described
10 embodiments staples or clips may be used in place of the sutures. Pledgets or anchors 89 may be attached to the free ends of the sutures to prevent them from sliding through the tissue. Over time, the serosal and/or mucosal tissue layers contacting one another as a result of the plications will knit together at regions labeled 90 and thereby increase the strength of the plications. This embodiment may be varied by eliminating the ring 81, and by simply
15 using the plications to create the narrowing in the stomach that retains the hourglass liner 80 and the pouch 2.

Fig 12 shows a variation of the Fig. 11 configuration in which all components may be implanted endoscopically, thereby eliminating the need for a laparoscopic or surgical step. In the Fig. 12 embodiment, the ring 81 is positioned *within* the stomach, surrounding the
20 hourglass liner 80 and pouch 2 as shown. Plications 88 are formed using sutures 87 (or clips, staples, etc.) applied from within the stomach to retain the ring 81 as shown. In the Fig. 11 and 12 embodiments, bioabsorbable sutures may be used such that once knitting occurs across the plications, the sutures may be absorbed by the body, leaving the ring 81 captured by the body tissue alone. Although in each of the Fig. 10 – Fig. 12 configurations the ring 81
25 may be proportioned to affect stomach function or eating behavior, it may be desirable to proportion the ring 81 to have no such effect, so that when the pouch 2 is removed by the physician, the ring 81 may be left in place without interfering with normal eating by the patient.

Fig. 13A is a top perspective view looking down into a stomach. The figure shows
30 plications 88 used to retain the ring 81. The plications 88 may be spaced apart around the circumference of the ring 81 as shown. Fig. 13B illustrates that the sutures may be passed

through only the interior mucosal layer of tissue as indicated by suture line 87a, or through the interior mucosal and exterior serosal layers of tissue as indicated by suture line 87b.

As discussed in connection with Figs. 11 and 12, the ring 81 may be used to “shape” the stomach in order to restrain a restrictive device and/or associated component (e.g. liner 80) against migration within the stomach. As another example shown in Fig. 13C, the ring 81a may be more disk-like and include windows 91 for receiving the plication tissue as well as an integral or detachable restrictive orifice 93. Preferably, the exterior perimeter of the ring seals against the surrounding tissue sufficiently to prevent passage of large amounts of food between the perimeter and adjacent tissue.

The ring 81 may also function as an anchor to which the implant may be attached using sutures, clips etc. In yet another alternative shown in Fig. 13D, bars 85 (or hooks, individual rings, hooks, buttons, barbs etc.) may be supported using tissue plications 88 and a restrictive device may be mounted to them during the same or a subsequent procedure. Because each of these embodiments relies primarily on tissue plications to support the implant, reliance on sutures or clips to connect the implant to the tissue may be minimized or even eliminated. This may in turn increase the amount of time that the implant will remain in place within the stomach.

Figs. 14A and 14B illustrate that a plication 88 may be formed without a ring, bar or other component simply by forming a fold in the tissue and passing a suture 87 through the fold. Pledgets 89 may be connected to the ends of the suture 87 to prevent it from slipping out of the tissue. The plications 88 may be used to “shape” the stomach to support the liner 80 as shown, such as in an arrangement similar to those shown in Figs. 11 and 12.

Figs. 15A and 15B illustrate methods of forming plications in tissue. An endoscopic grasper 100 (Fig. 15A), corkscrew mechanism 102 (Fig. 15B), vacuum device 104 (Fig. 15B) or alternative device is used to pinch folds 106 of tissue, and then sutures (or clips, staples etc.) are passed through the folds 102 to draw the folds into contact with one another into the configuration shown in Fig. 13B. Over time, the tissue held together by the sutures knits together, thereby creating a much stronger bond between the tissues than would be achieved using sutures alone. If desired, dissolvable or bioabsorbable sutures may be used to create the plications.

The orientation of the plications may be selected depending on the purpose to be achieved by the plications. Referring to Fig. 16A, plications 88a may be formed to have a more vertical orientation (i.e. more or less radiating away from the gastro-esophageal junction) as opposed to the more horizontal plications shown in prior drawings which may line up somewhat circumferentially around a portion of the stomach. Such plications 88a may be formed by drawing folds 106 of tissue around a mandrel 108 and then attaching the folds together using sutures 87. The mandrel may then be removed, leaving a tunnel 110 in its place. Fig. 16B shows an example of an implant 112 having members 114 proportioned to be inserted into four such tunnels 110 formed in a stomach. The implant 112 may be a ring to which other implants such as satiation devices may be attached or it may itself be a satiation device. Members 114 are inserted into the tunnels 110 as shown in Fig. 16C to secure the implant in place. Soft stops 115 at the ends of members 114, which deform for passage through the tunnel expand upon exiting the tunnel may be optionally provided to prevent upward migration of the ring.

Fig. 16D illustrates formation of plications using a surgical stapler 117 approaching the exterior surface of the stomach. As shown, the stapler 117 is provided with staples 119 in the distal most portion of its jaws, but there are no staples in the more proximal portion 121 of the jaws. To form a plication, the jaws are clamped onto a section of stomach tissue and staples 119 are passed through the tissue. As shown in Fig. 16E, the section of tissue 123 that was within proximal portion 121 (Fig. 16D) of the jaws is not stapled, and thus forms a tissue tunnel 118 similar to the tunnel shown in Fig. 16A.

Fig. 16F shows an alternative form of implant 112a being retained by the plications 88a. The implant 112a includes members 114a that may be inserted into the tunnels 110a of the plications 88a. Alternatively, the implant may be positioned before the plications are formed, in which case the plications 88a may be formed around the members 114a. The members 114a may be long enough to be retained in tissue tunnels formed well into the stomach, such as in the antrum, the fundus or other regions of the stomach while still positioning the restrictive orifice of the device in the proximal stomach. Alternatively, the members 114a may be shorter for retention by plications in the gastro-esophageal junction region or other proximal portions of the stomach. This concept of retaining the implant using tissue plications may be applied to implants positionable in other regions of the stomach (and

throughout the body) as well, and is not limited to use with implants that have restrictive orifices in the proximal stomach.

Fig. 16G is a cross-section view of a portion of a stomach wall, illustrating that the vertical plications 88b may be formed from within the stomach. This may be performed using an endoscopic staple, suturing device, or clip applicator introduced transorally into the stomach. Figs. 17A through 19 show additional arrangements in which a ring or band may be used to facilitate retention of an implant. In the arrangement of Fig. 17A, rings 81 or restrictive bands are positioned above and below an implant 2a to provide "stops" that prevent proximal and distal movement of the device within the stomach. A similar configuration using only a ring 81 below the implant 2b is shown in Fig. 17B. As a third alternative, the rings 81 may be eliminated and plications may instead be formed in tissue above and below (or only below) the implant to prevent its migration.

In Fig. 18, a ring 81 or band is again positioned below the implant to create a stop against distal migration of the implant. In this configuration, the implant 2c may take the form of an inflatable or self expanding balloon 92 that is free floating in the region above the ring 81. The balloon 92 occupies a large percentage of the gastro-esophageal junction region and thus restricts food intake by only allowing food to pass through the spaces between the balloon and the surrounding body wall as indicated by arrows.

Fig. 19 shows another variation of the Fig. 17B embodiment in which the ring 81 includes magnetic elements that are of the same polarity as magnet elements in the proximal portion of the implant 2d. Thus, repulsive forces between the implant 2d and the ring 81 prevent distal movement of the implant 2d.

Fig. 20 shows an arrangement of components intended to form a framework within the stomach that an implant device may later be attached to. The components include a mesh band 116 positionable around the interior wall of the stomach. Interior pledgets 118 are spaced apart along the interior wall of the mesh band 116. Exterior pledgets 120 are spaced apart along the exterior wall of the stomach. The pledgets 118, 120 are connected to the mesh band by sutures 122. Over time, the mesh band will migrate into the wall tissue. Exterior pledgets 120 prevent the mesh band from migrating completely through the wall tissue, while the interior pledgets 118 prevent the mesh band from moving inwardly and separating from the wall tissue in the stomach interior. Eventually, the mesh band will

become encapsulated within the wall tissue and form a sturdy structure to which implants such as pouch 2 may be attached using sutures, clips or other devices.

5 *Restrictive Devices*

The flexible nature of the pouch 2 allows it to move in response to stomach movement, thereby producing little or no stress on the sutures or anchors holding the pouch in place. This is believed desirable towards minimizing the chance that the implant will detach from the stomach wall. Other restrictive devices and methods of retaining them are
10 shown in Figs. 13C, 17A, 17B, 18 and 19.

Figs. 21A through 21D show restrictive devices having alternative features which may likewise minimize risk for detachment. These devices may be used with or without the various attachment devices described in this application.

Fig. 21A shows a rigid ring 124 positionable in the gastro-esophageal junction region
15 and attached using sutures or other means similar to those described for pouch 2. The ring 124 may be flexible for endoscopic insertion, and then convertible (e.g. by inflation to a high pressure using a detachable inflation tube) to a rigid ring following implantation so as to restrict movement of the stomach. Such restriction of stomach movement is intended to minimize stresses on the sutures or anchors and thus reduce the risk of detachment.

20 Ring 124 includes a flow-restrictive orifice 126 through which food passes. If desired, the ring 124 may include a circumferential region surround the orifice 126 that is independently inflatable or deflatable to adjust the diameter of the exit orifice.

Fig. 21B shows an alternative restrictive device 128 which has a tapered configuration, such that forces imparted against the device by the stomach (as indicated by
25 arrows) as well as forces imparted by food passing through the tapered passageway 130 in the device 128 will cause the device to seat more tightly within the gastro-esophageal junction region. As with the other embodiments, sutures, anchors, clips, adhesives etc. may be used to attach the device 128 to the stomach walls.

Fig. 21C shows a restrictive device 132 that is pleated between anchor points 134.
30 The pleats allow the device 132 to expand in response to forces against it, and thus minimize

stress at the anchor points. As with the other restrictive devices, device 132 includes a restrictive orifice 136.

Restrictive device 138 of Fig. 21D is formed of a plurality of individual members 140, each of which is separately attachable to the tissue of the gastro-esophageal junction using sutures, clips or the like at anchoring points 142. The individual members 140 collectively form a restriction at the gastro-esophageal junction so as to minimize food intake by the patient. The amount of restriction may be reduced by reducing the size of the members 140. Because the individual members 140 are physically separate from one another, movement of the stomach will produce little or no stress on the anchors.

Tissue Modification to Increase Tissue Strength

If desired, the tissue of the stomach, esophagus, or gastro-esophageal junction may be treated using techniques such as mechanical abrasion, RF ablation/coagulation, or chemical abrasion that can strengthen the tissue such as by forming a layer of scar tissue.

Cyanoacrylate coatings or growth inhibitors may also be applied to the tissue to strengthen it. These forms of tissue modification may be used in embodiments in which implant devices are physically connected to the tissue using sutures, staples, etc, or in embodiments in which there is no such physical connection but in which increased tissue strength is desired for prevention of erosion.

Various components and methods have been described herein. These embodiments are given by way of example and are not intended to limit the scope of the present invention. It should be appreciated, moreover, that the various features of the embodiments that have been described may be combined in various ways to produce numerous additional embodiments. Also, while various materials, dimensions, shapes, implantation locations, etc. have been described for use with disclosed embodiments, others besides those disclosed may be utilized without exceeding the scope of the invention. For example, the retention methods and devices are not limited to use within the gastro-intestinal system and may be used for implants placed elsewhere in the body.

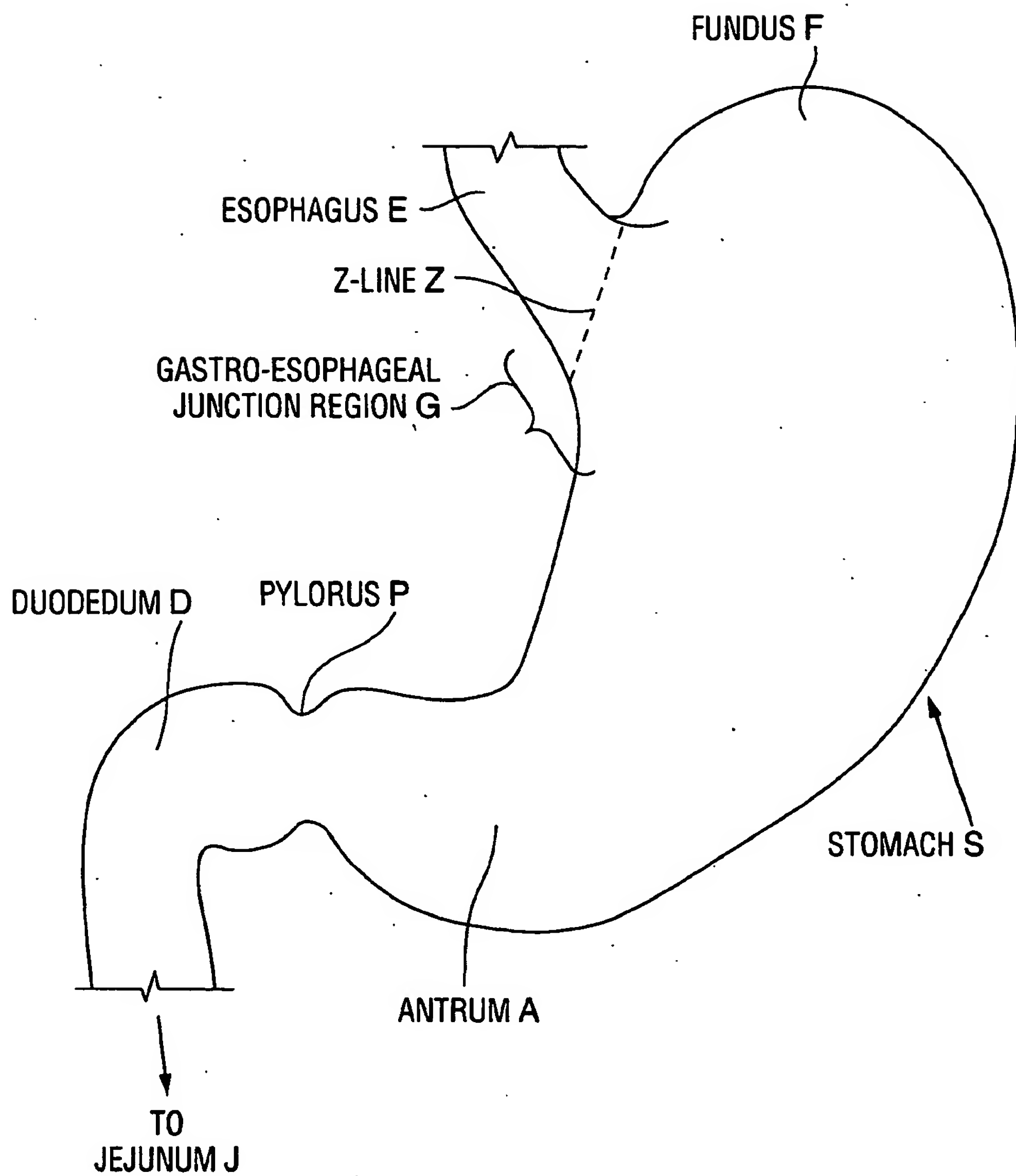


FIG. 1

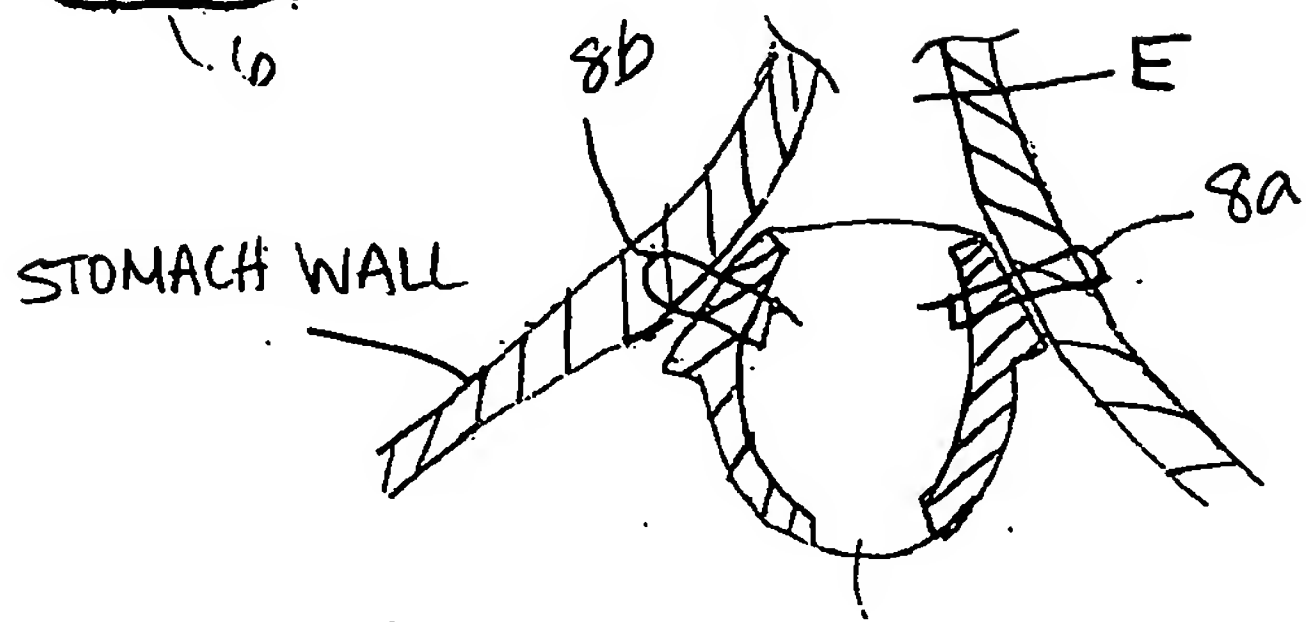
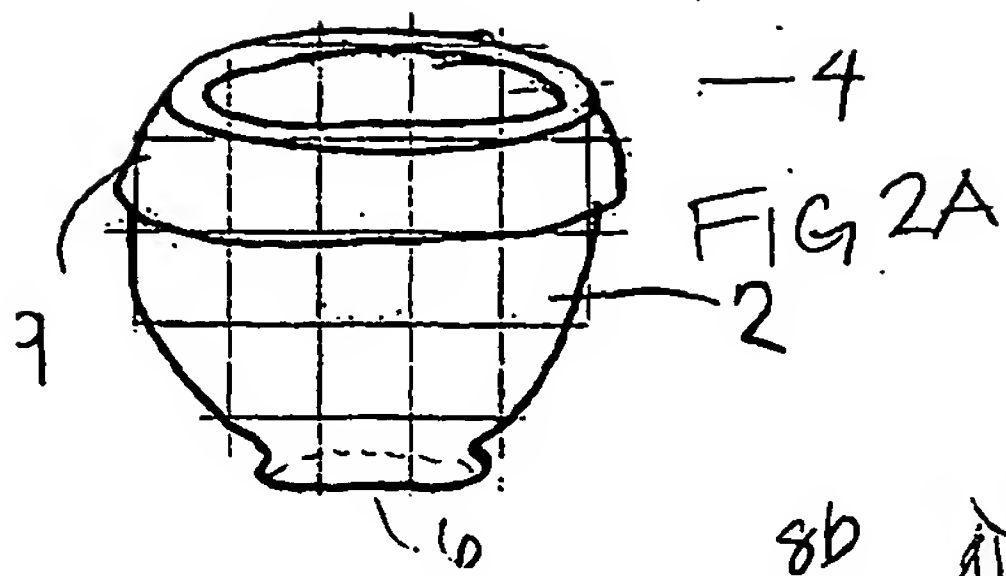
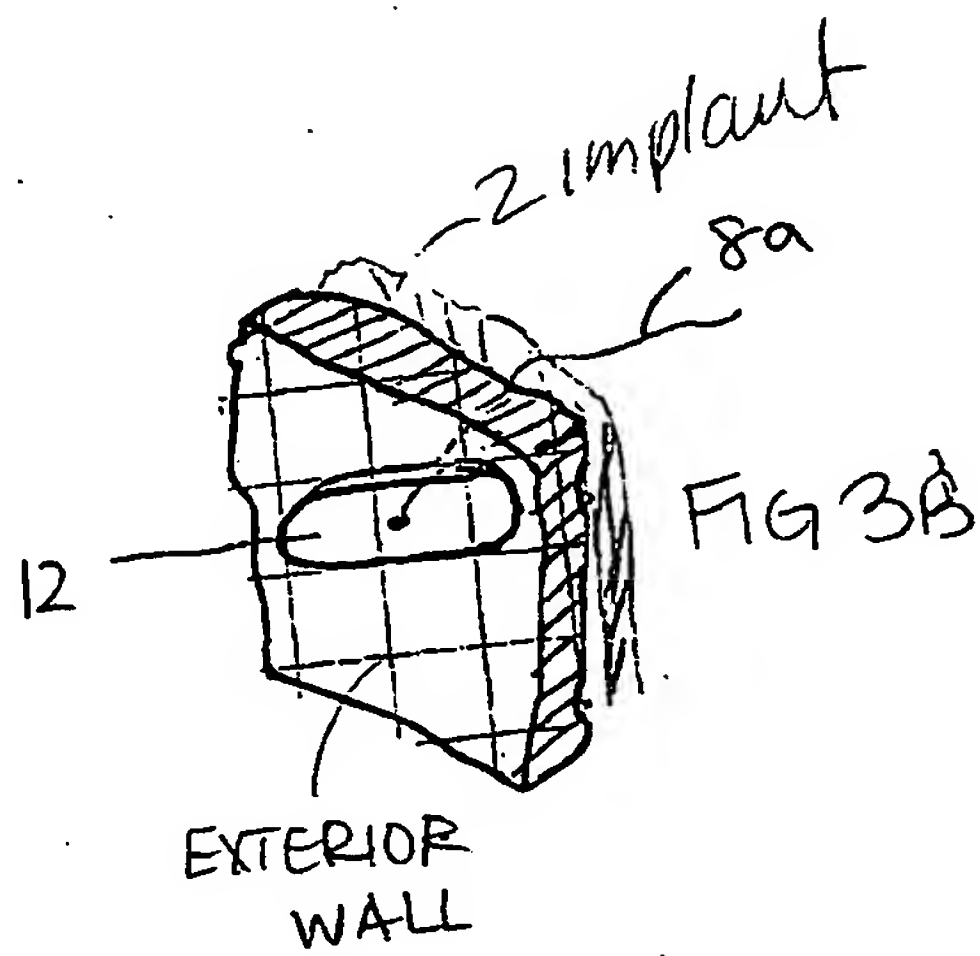
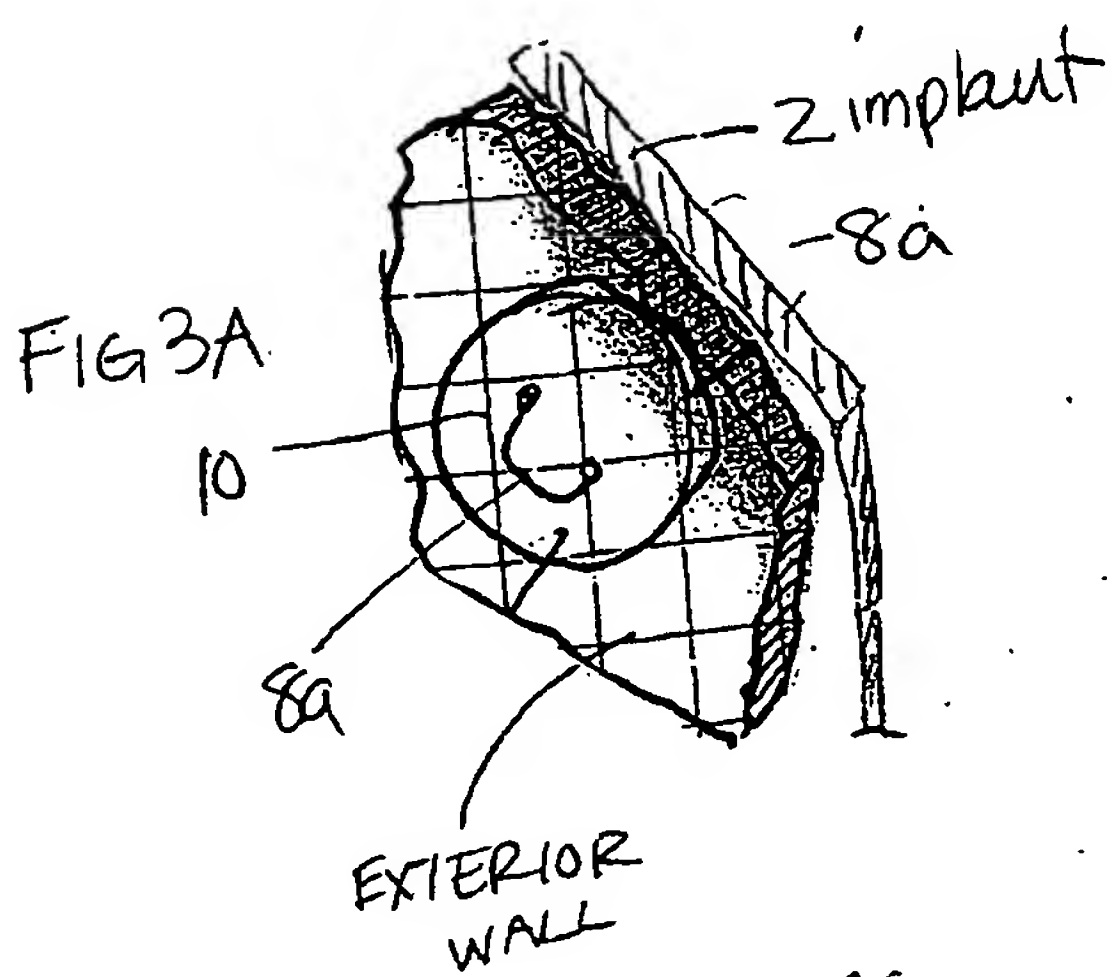


FIG. 2B



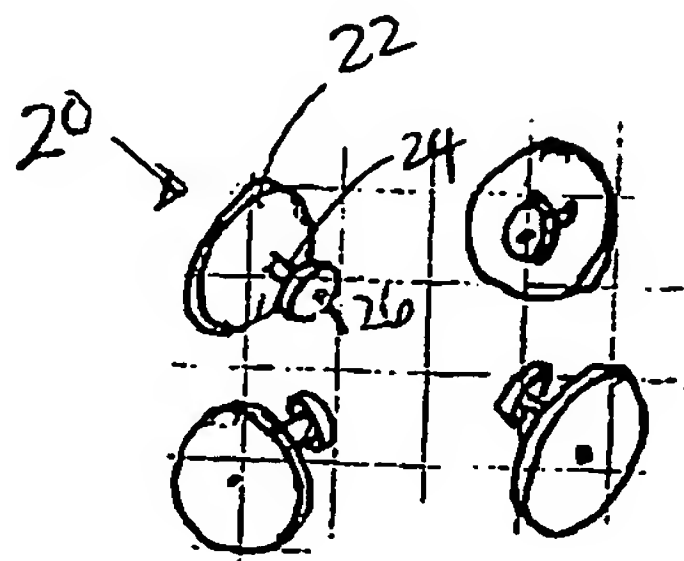
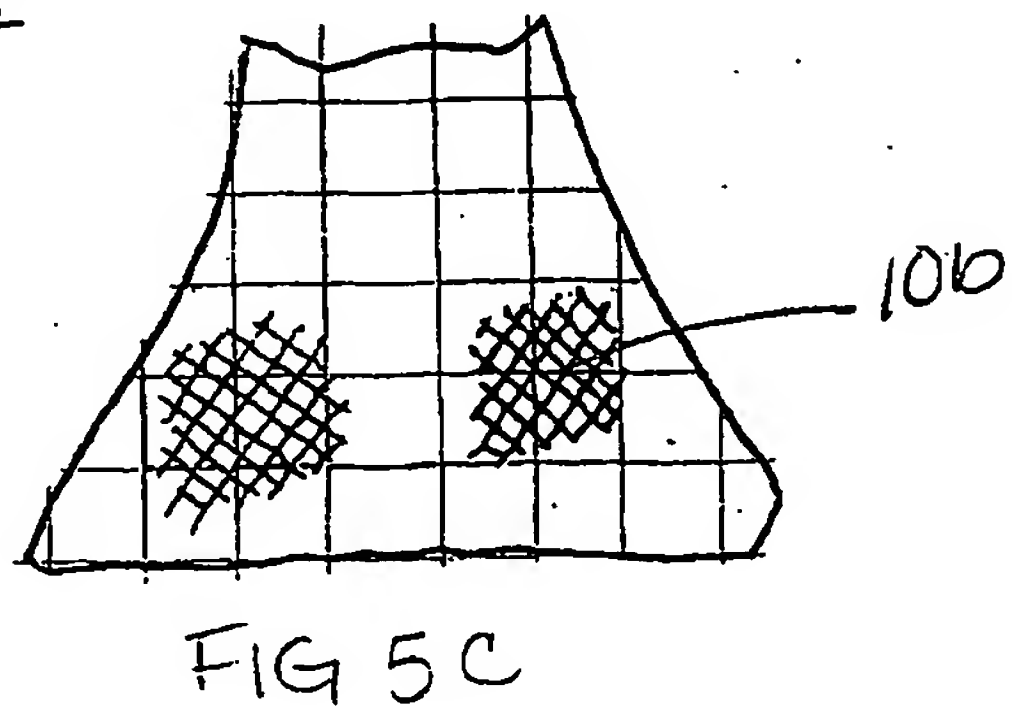
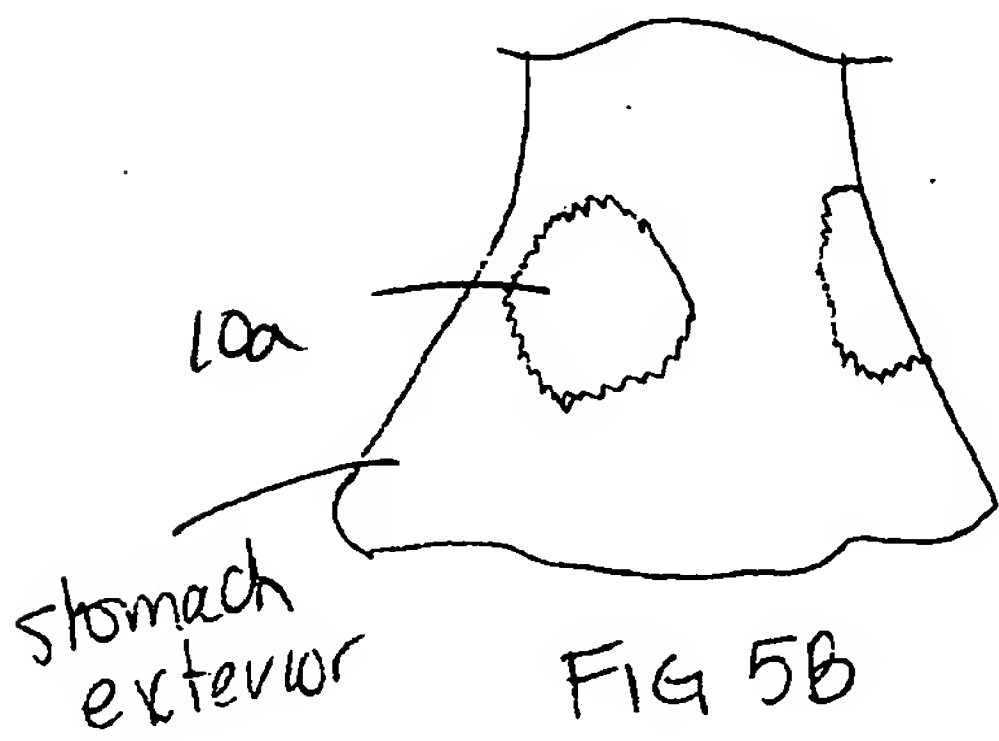
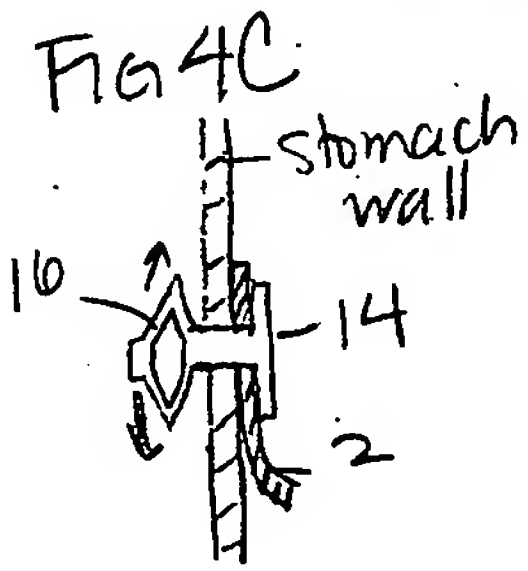
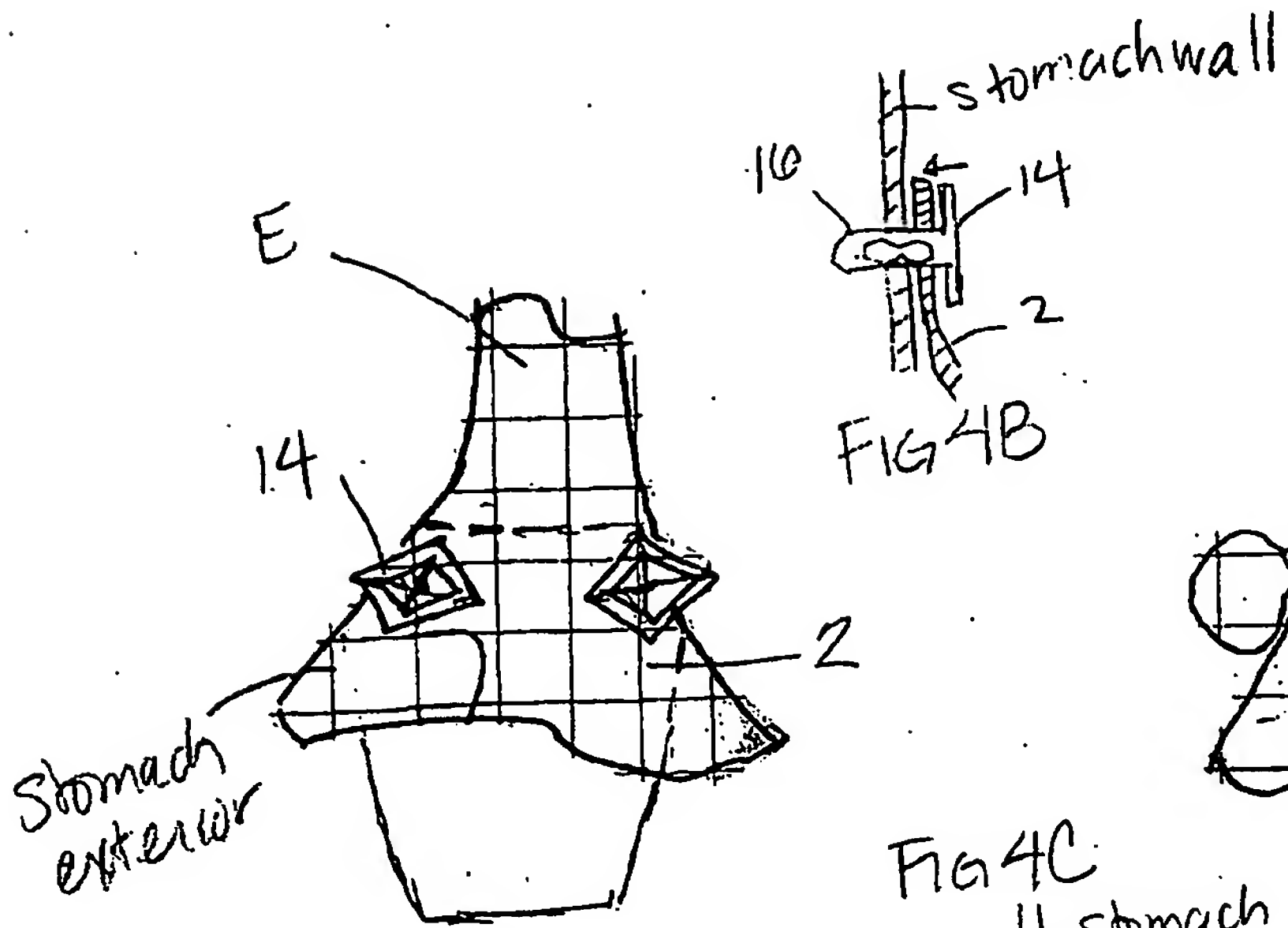
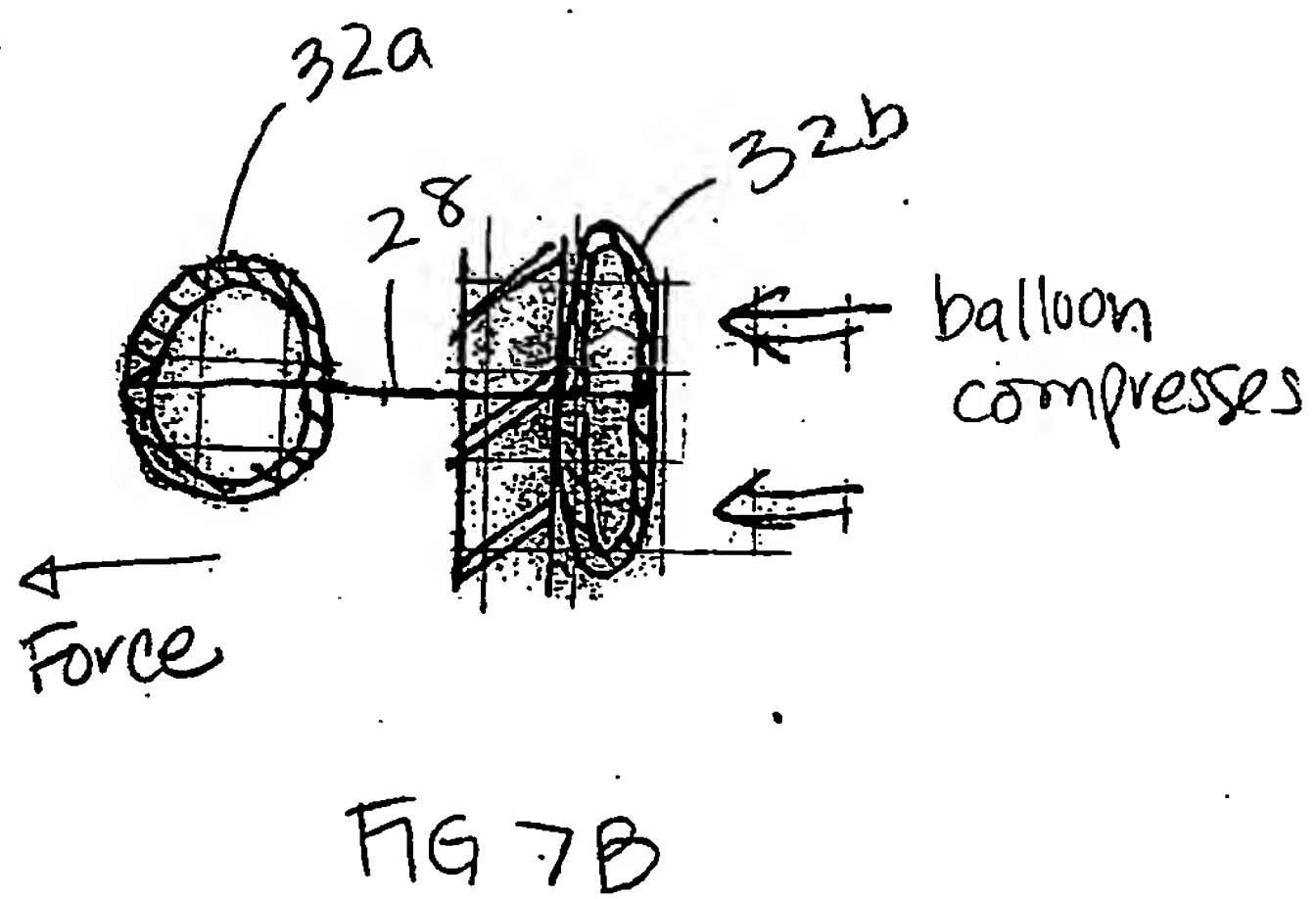
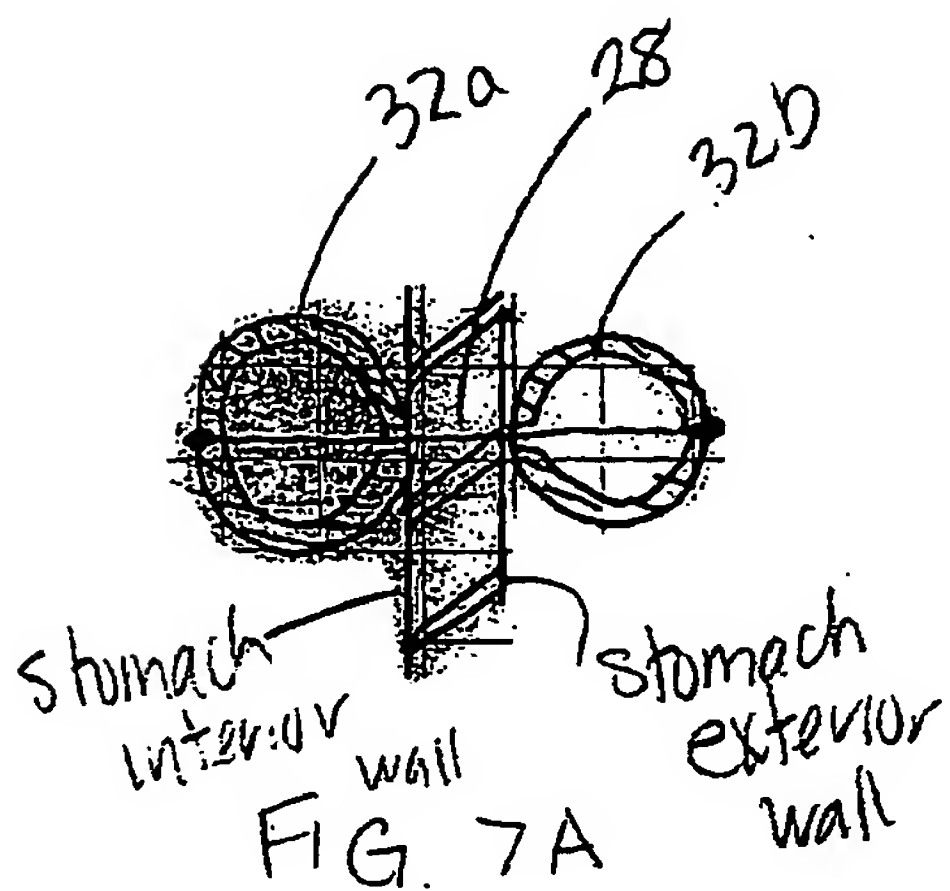
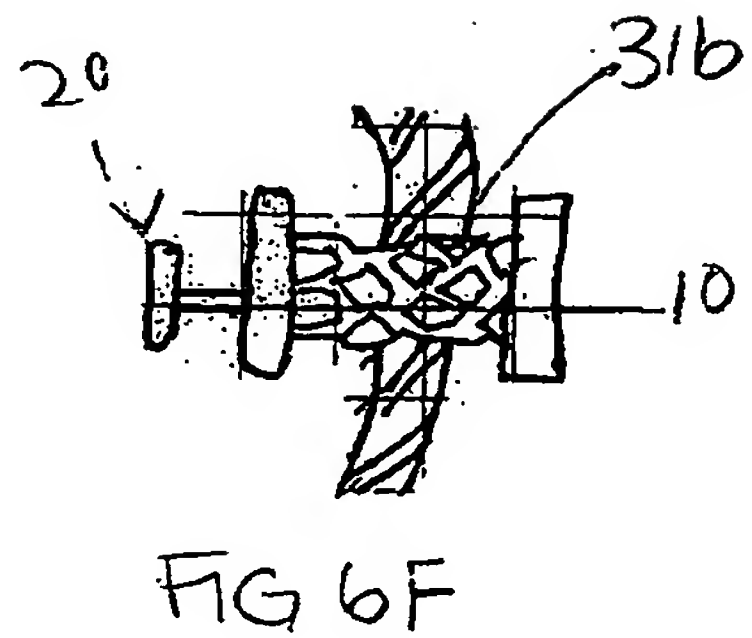
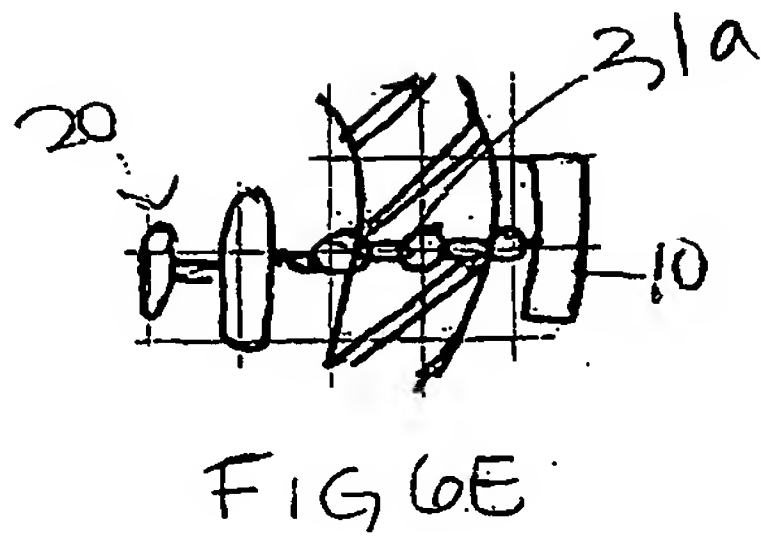
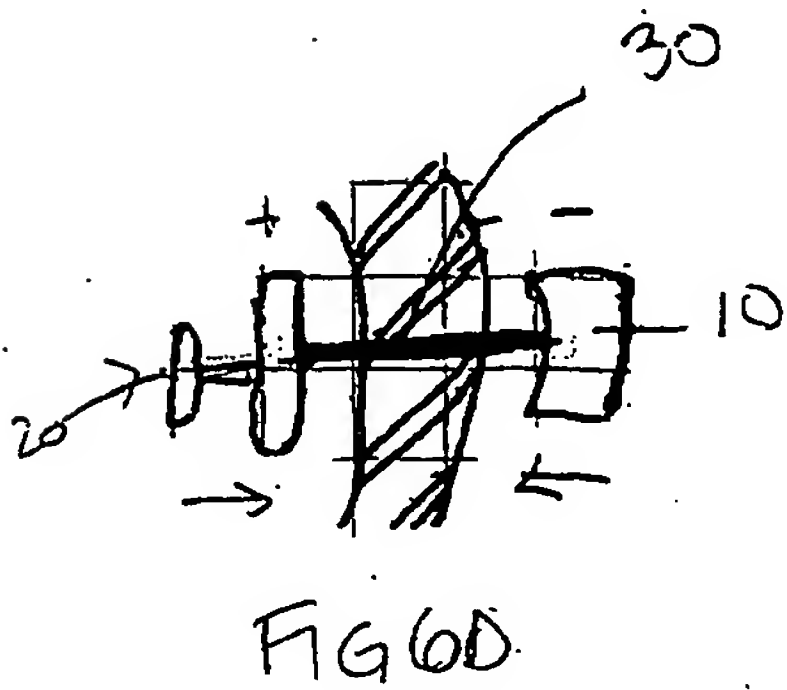
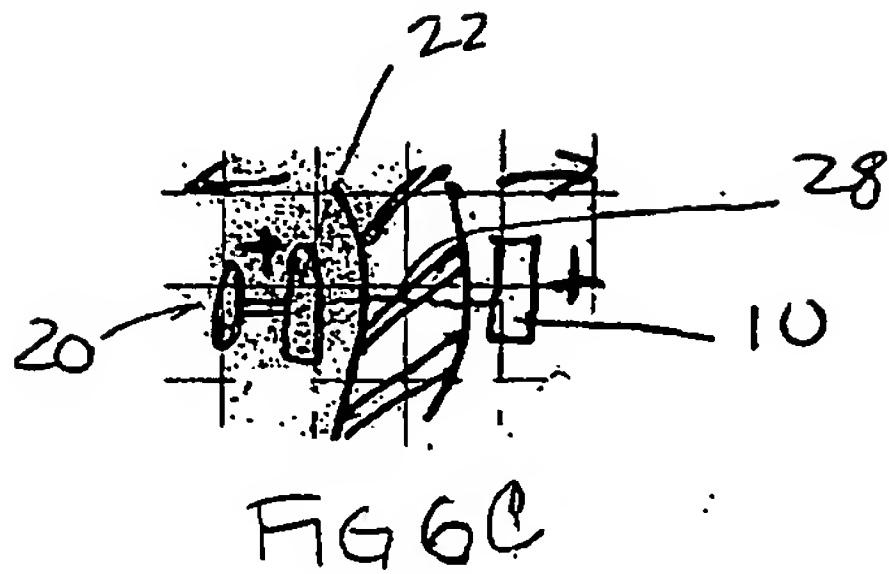
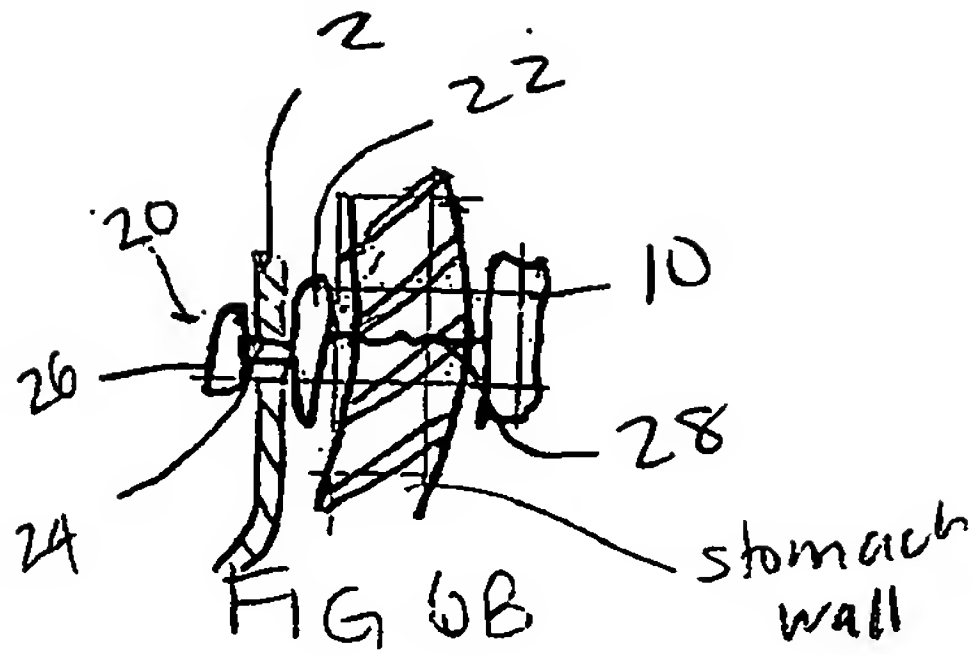
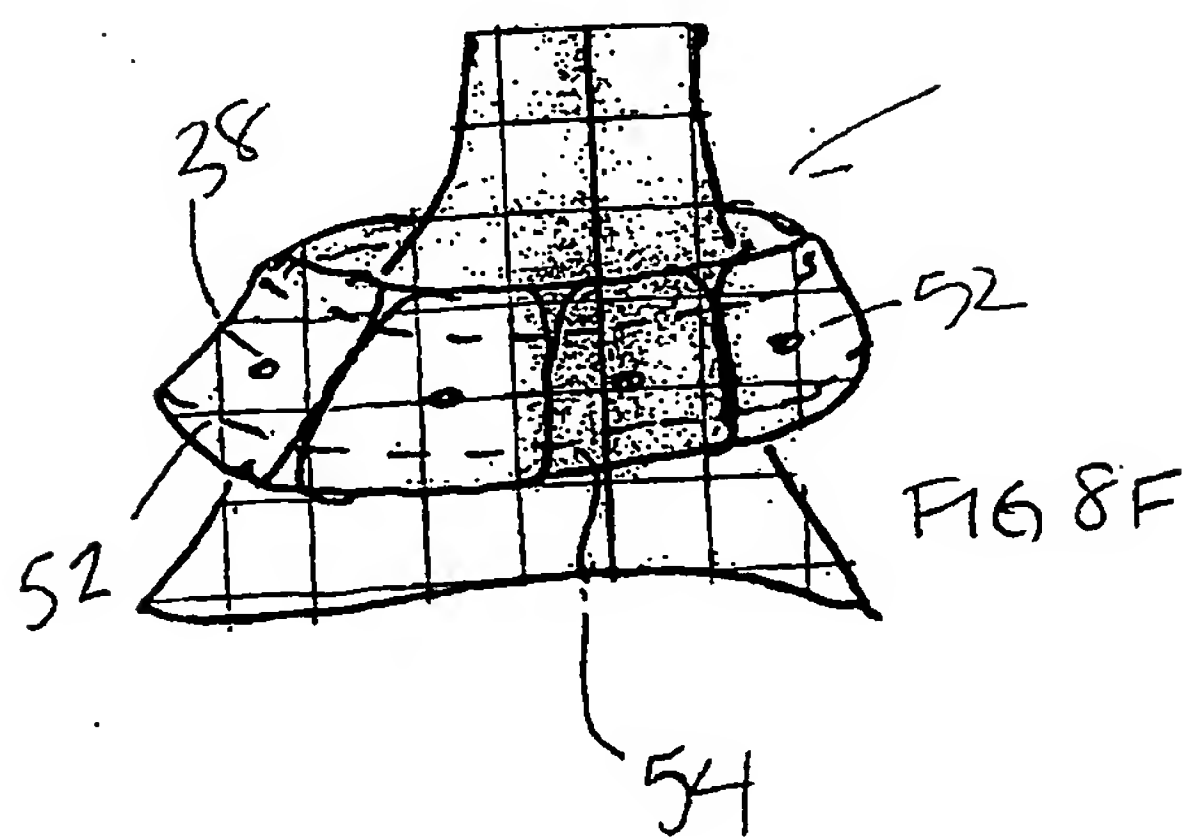
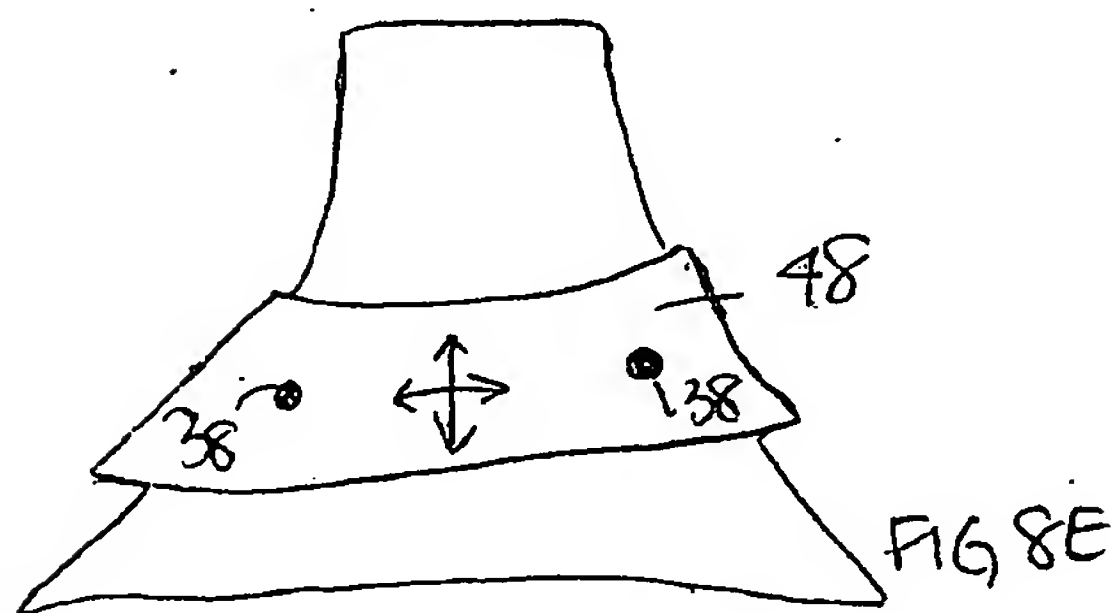
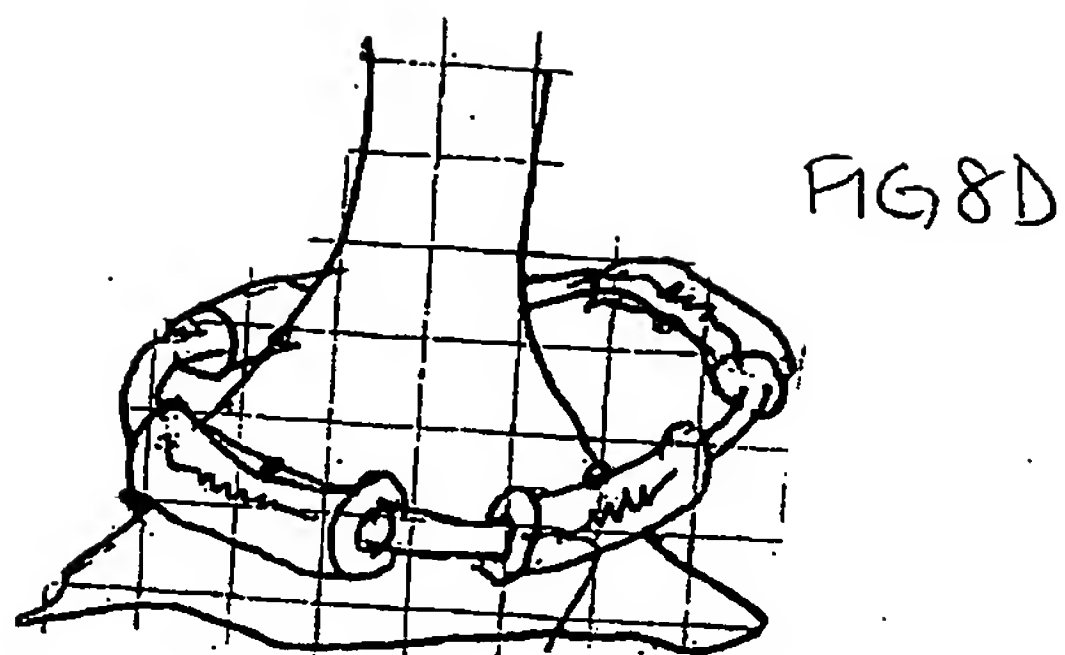
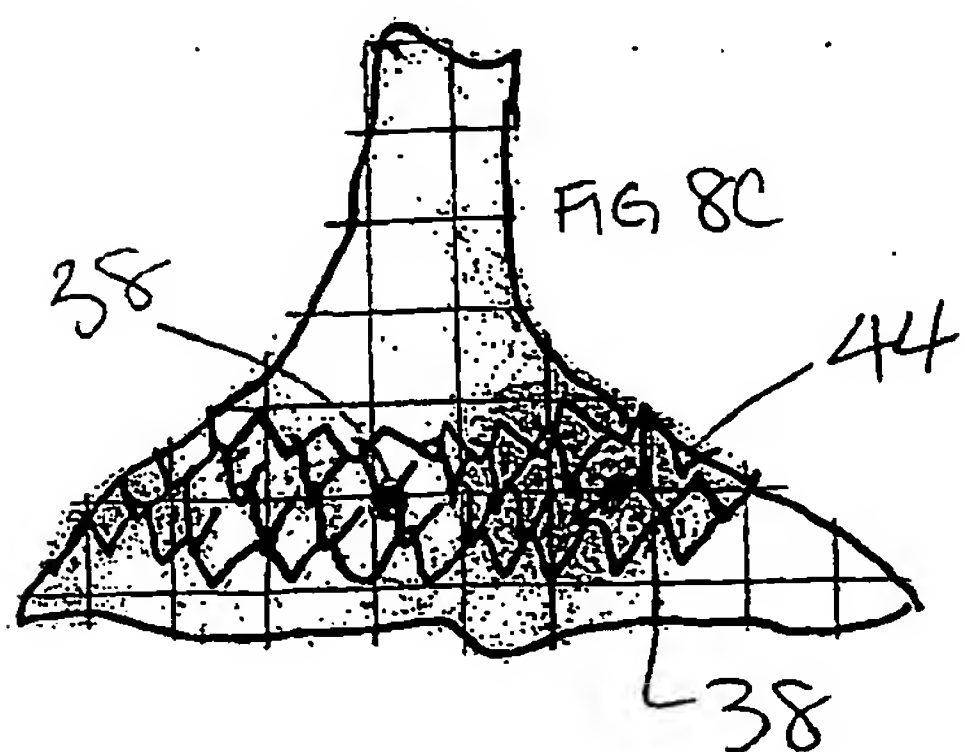
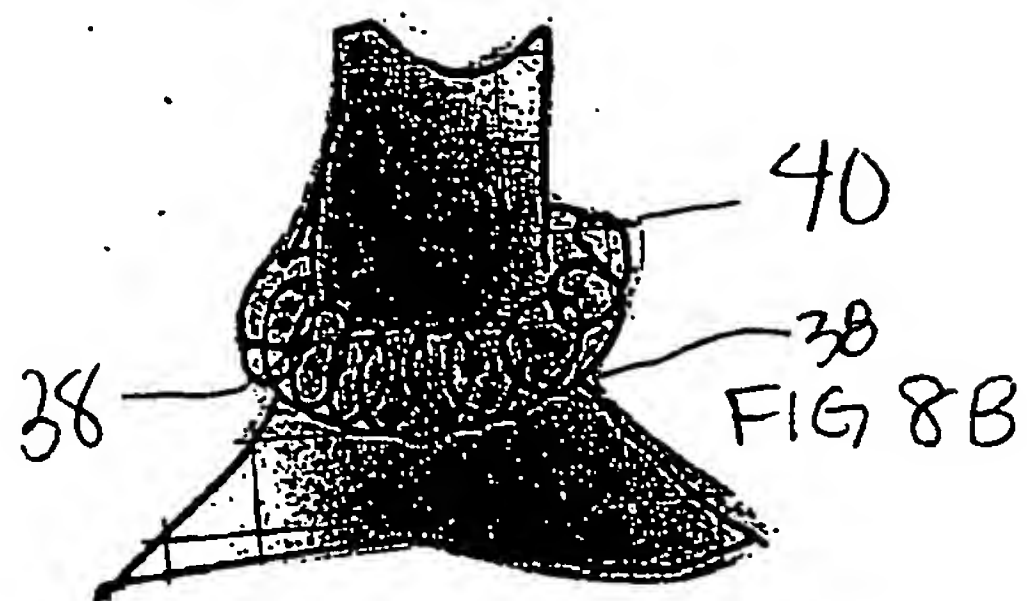
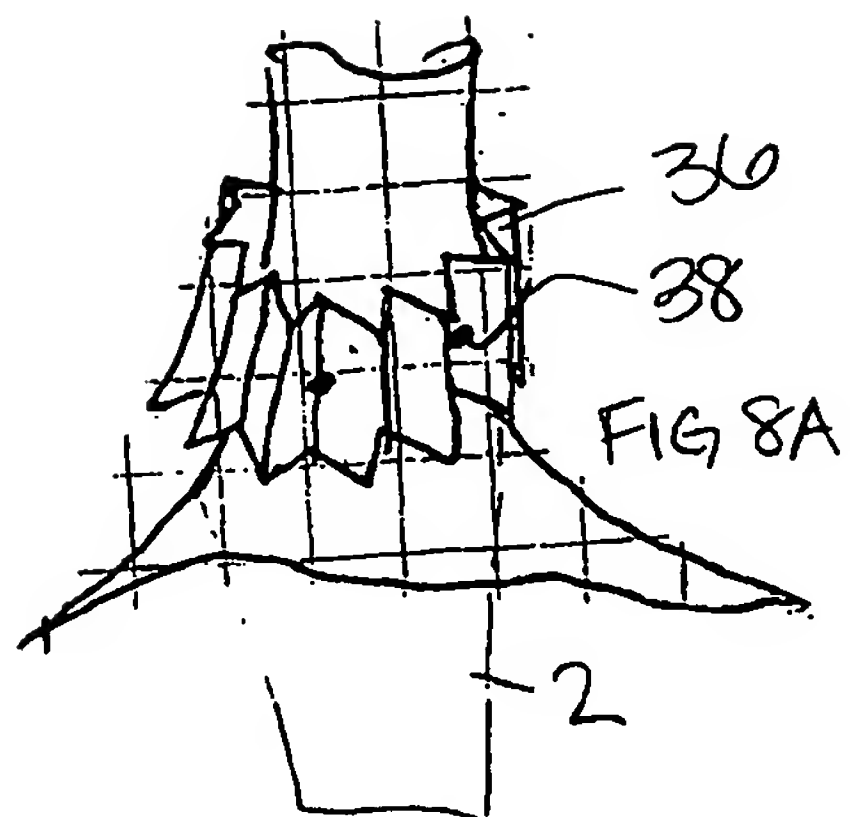


FIG 6A





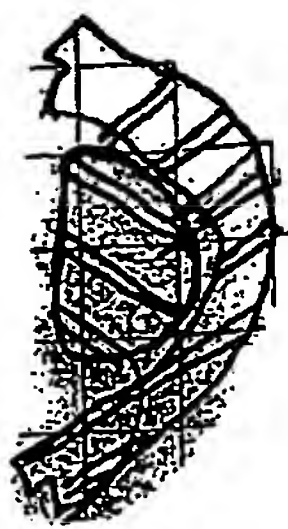
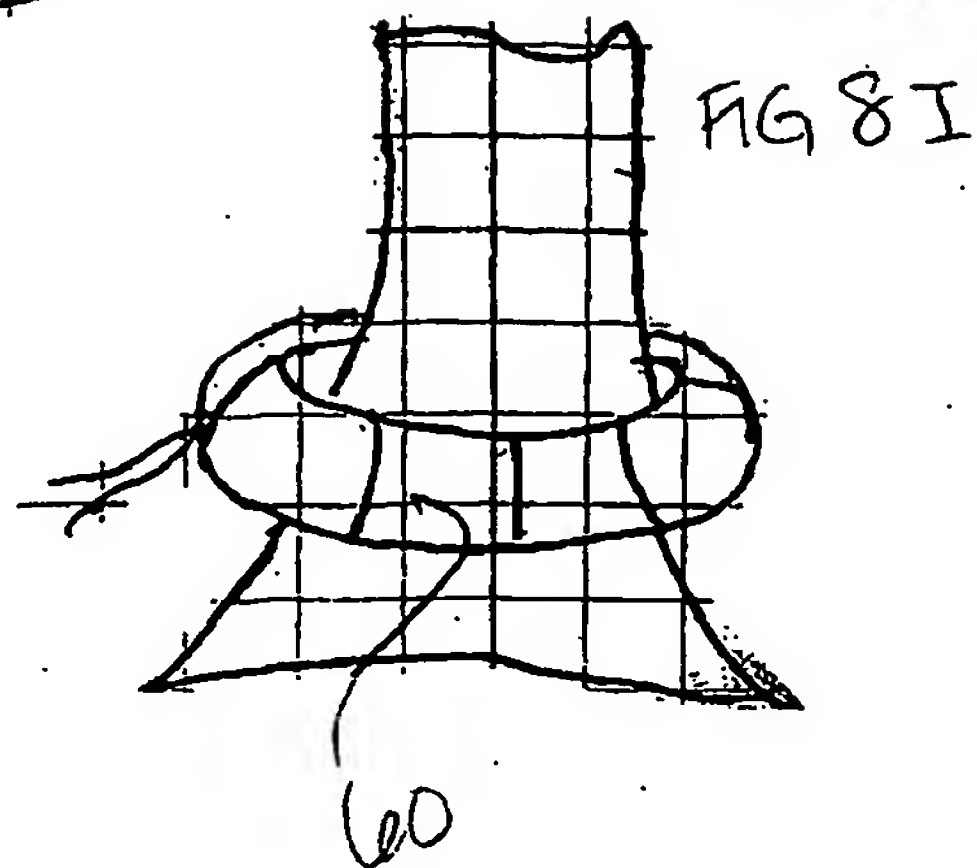
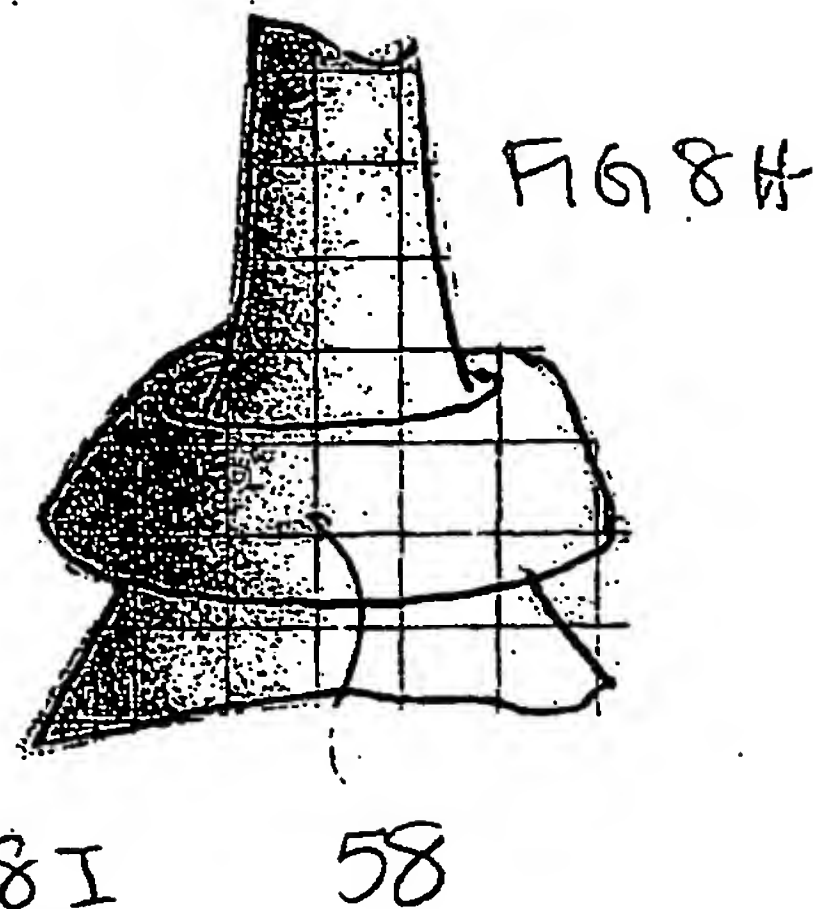
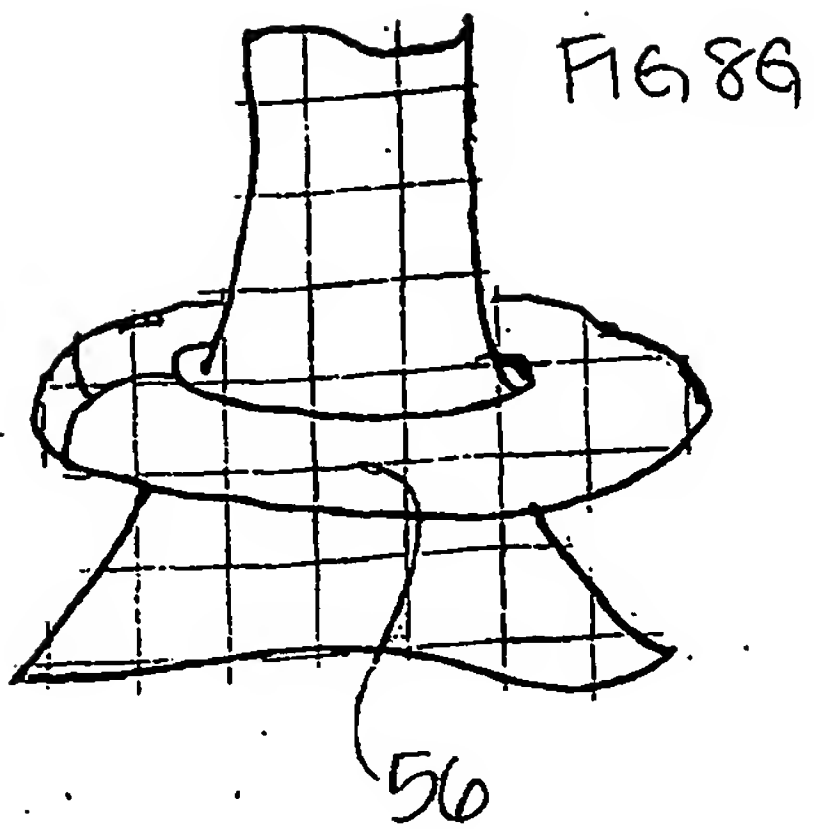


FIG 9A

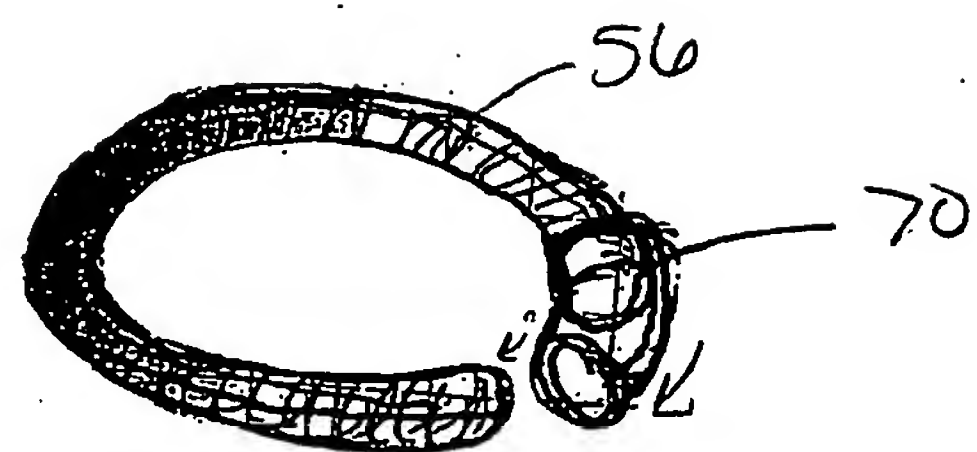
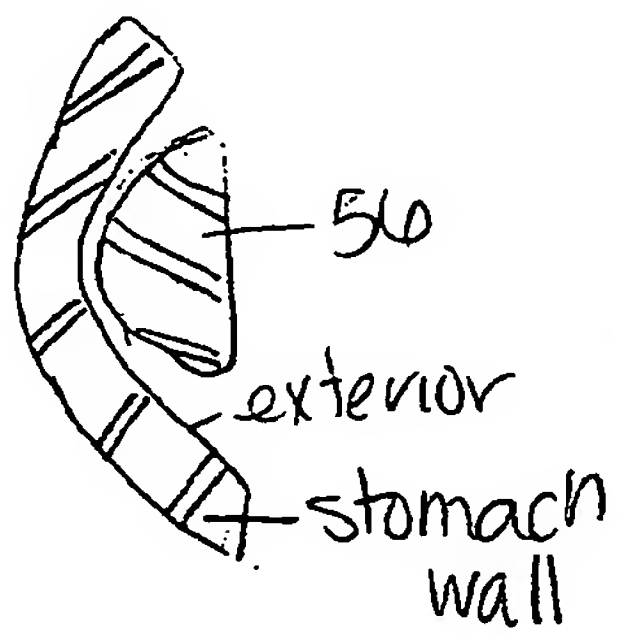


FIG 9C

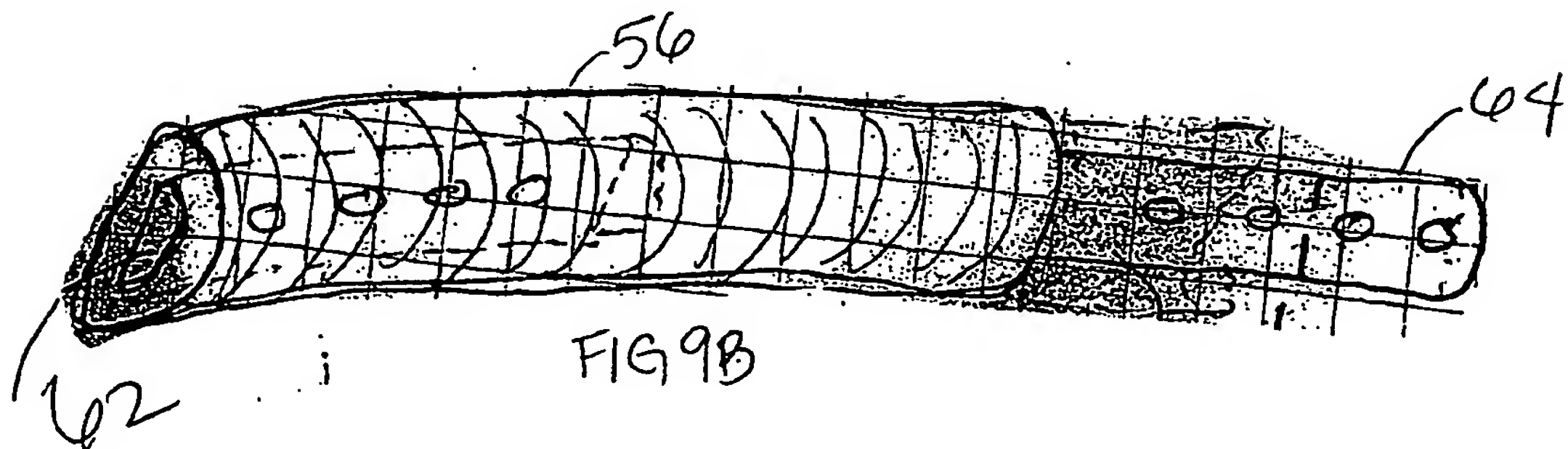


FIG 9B

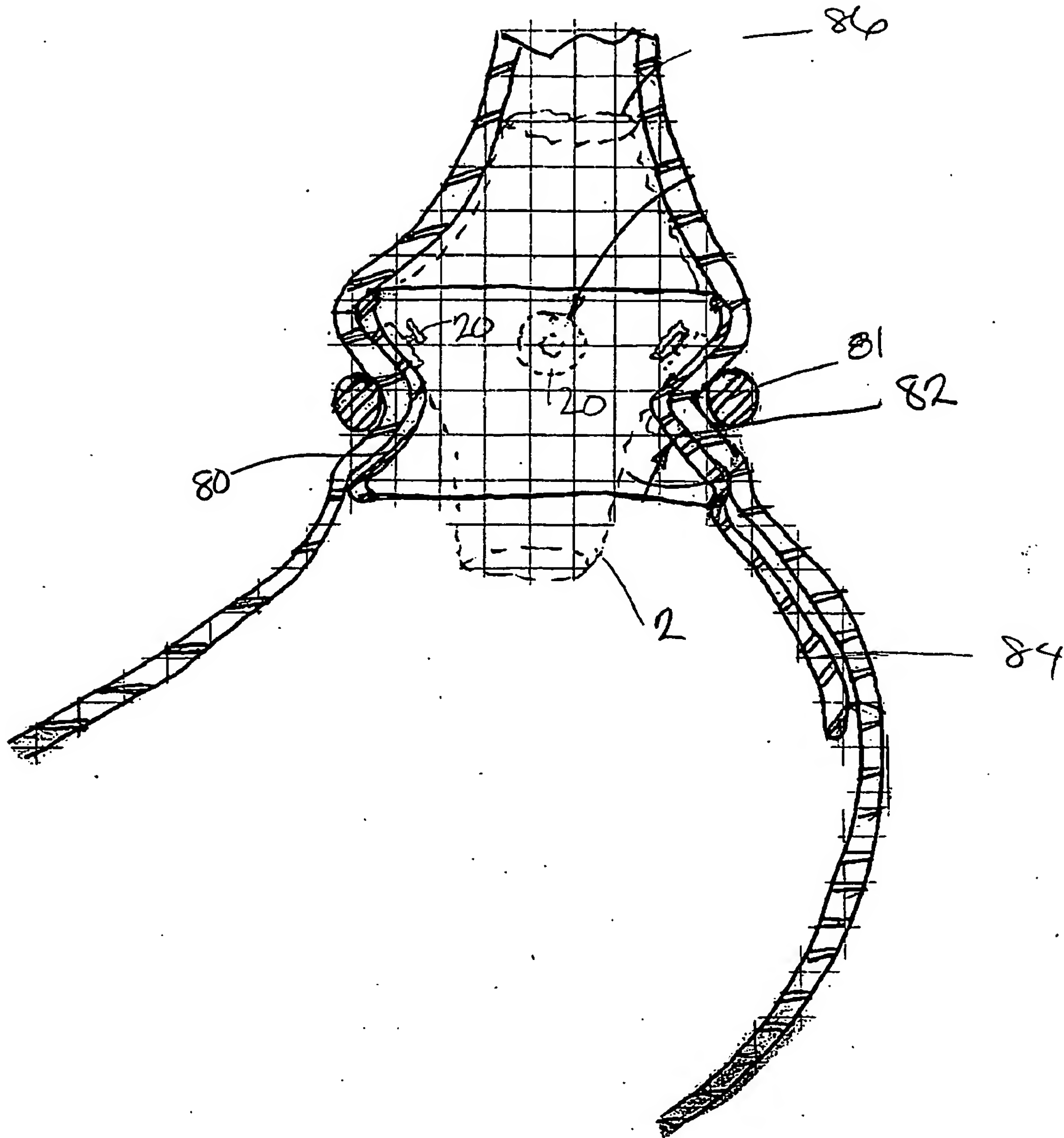
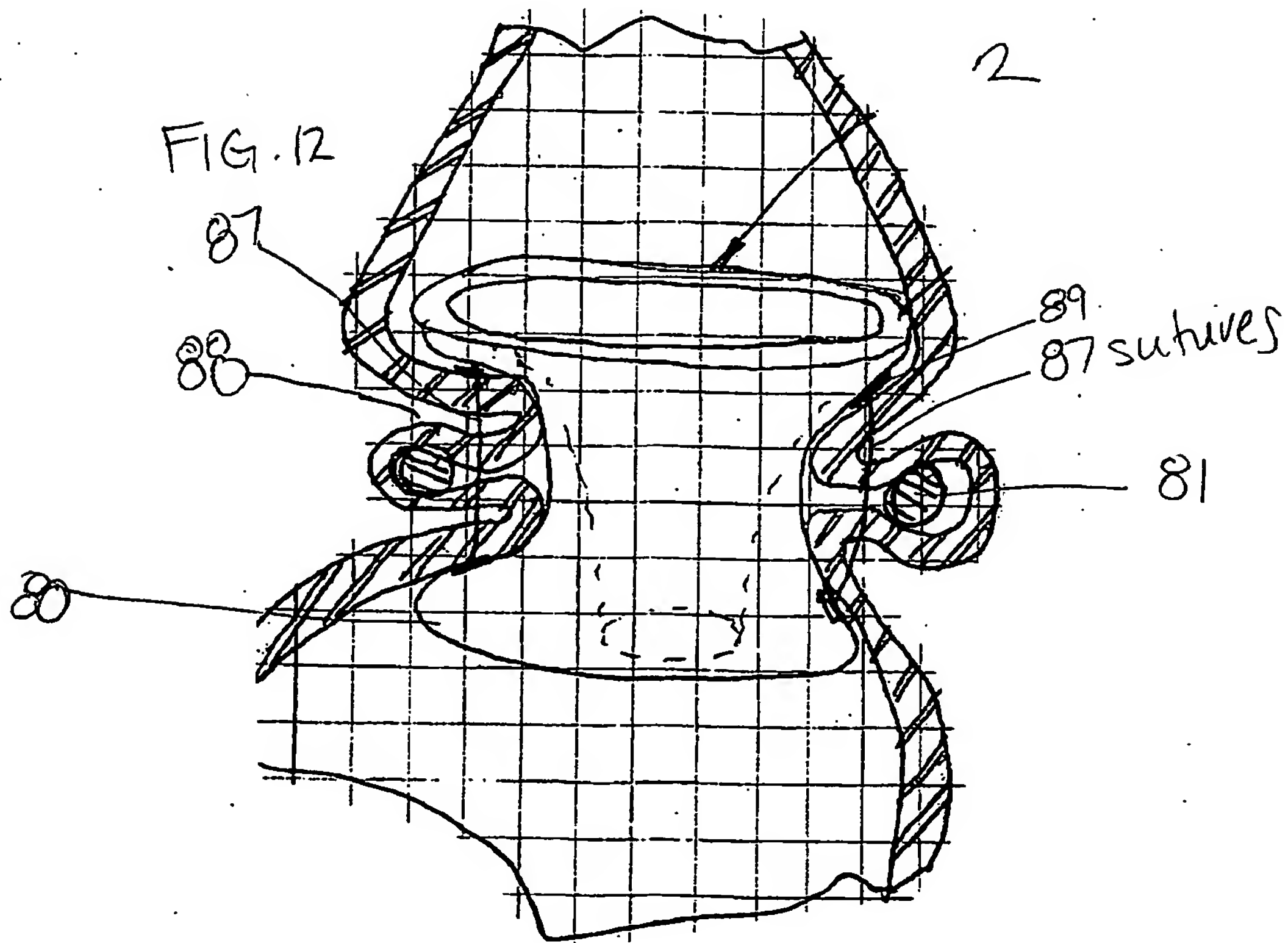
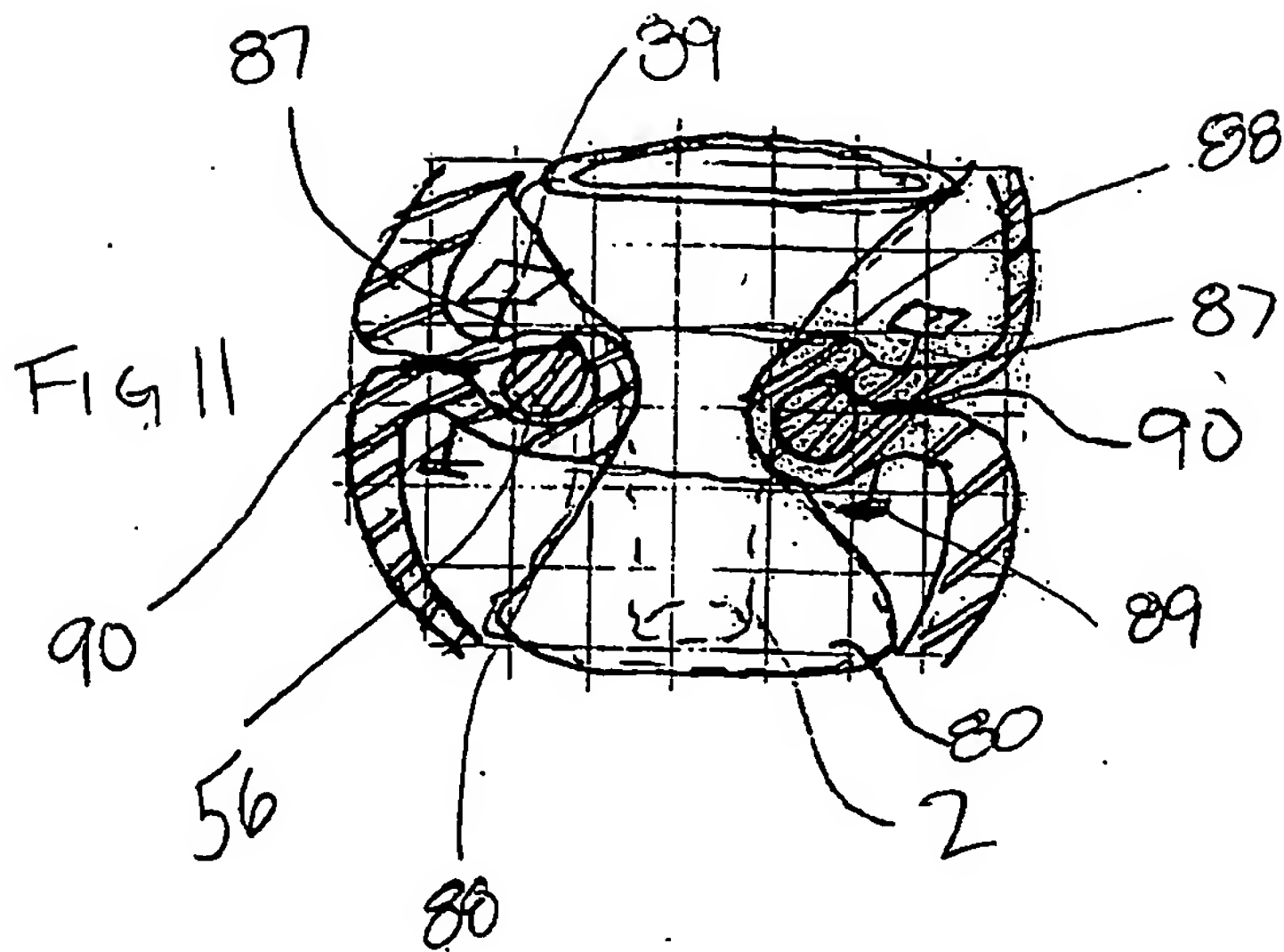


FIG 10



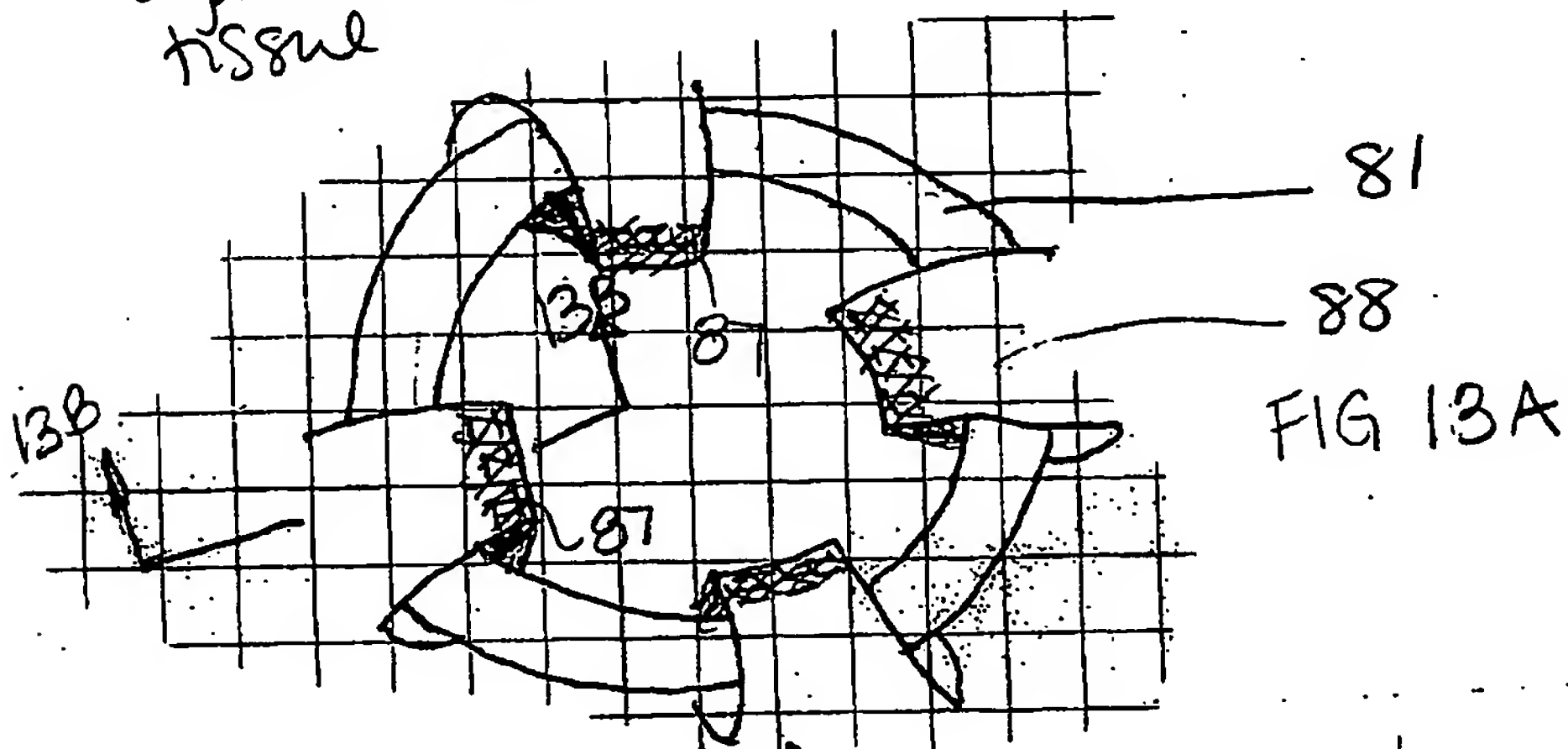
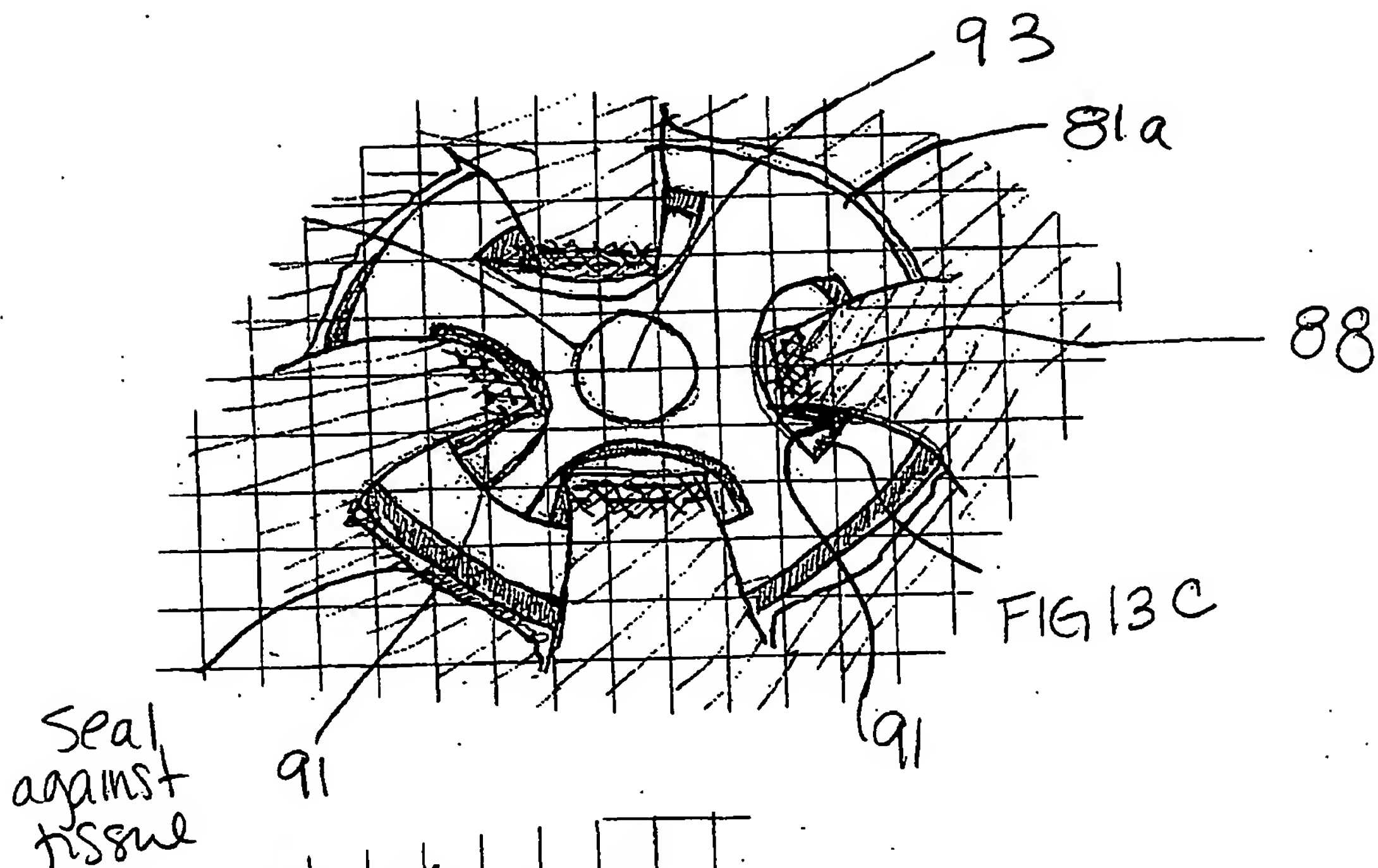
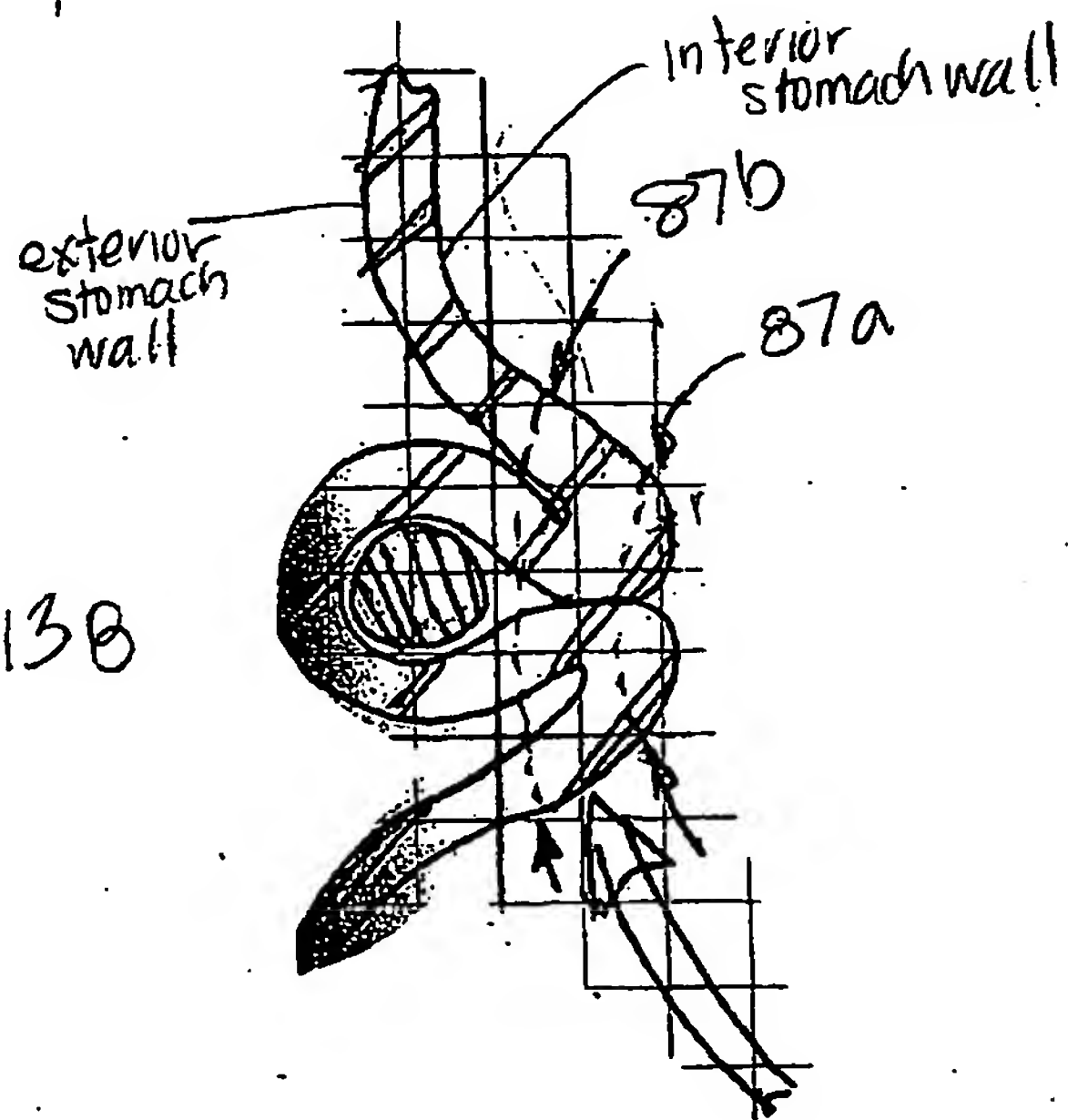


FIG 13B



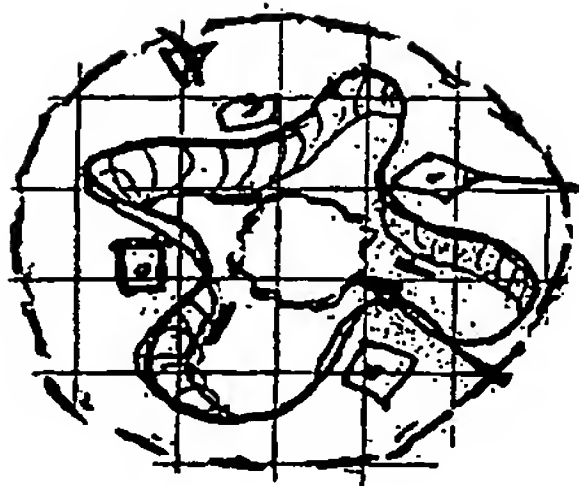
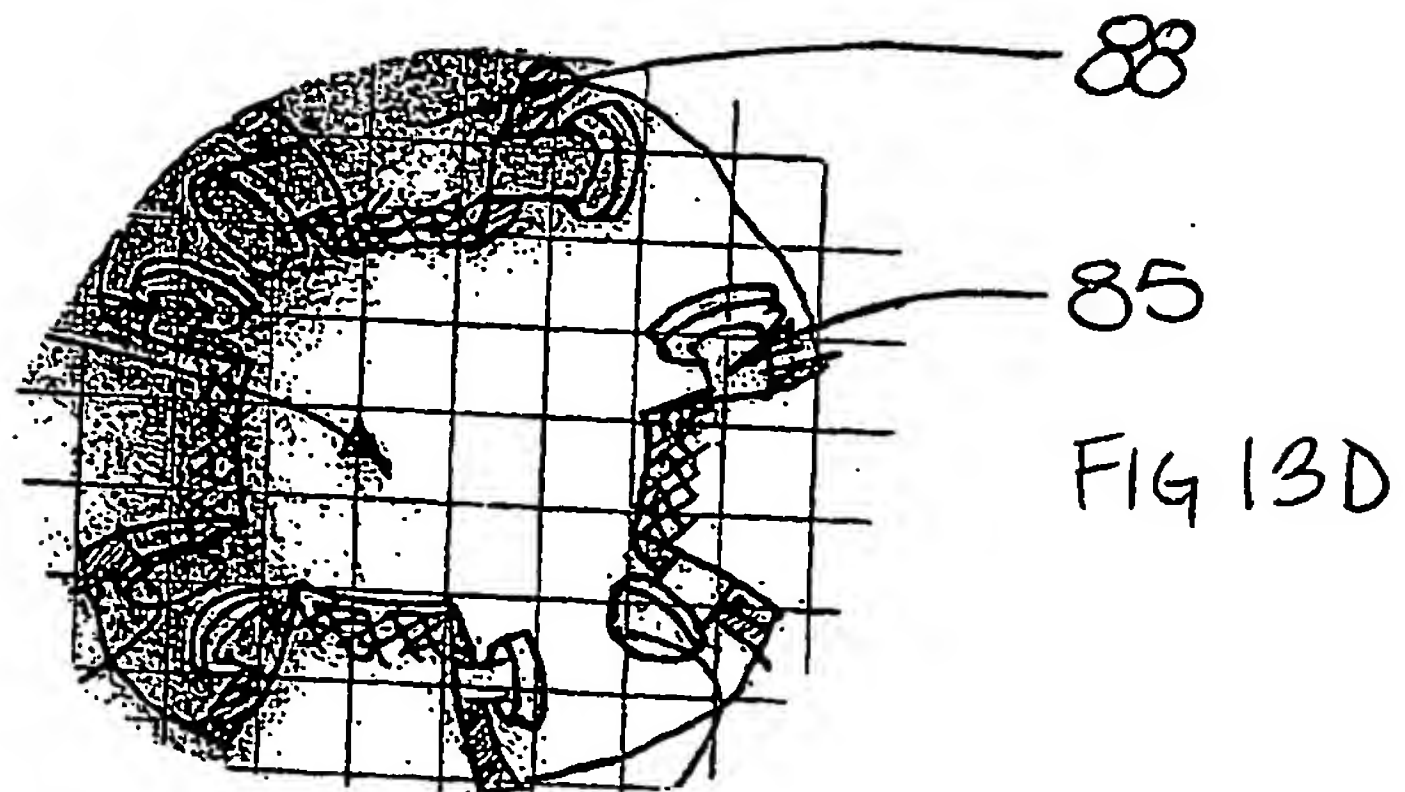


FIG 14A

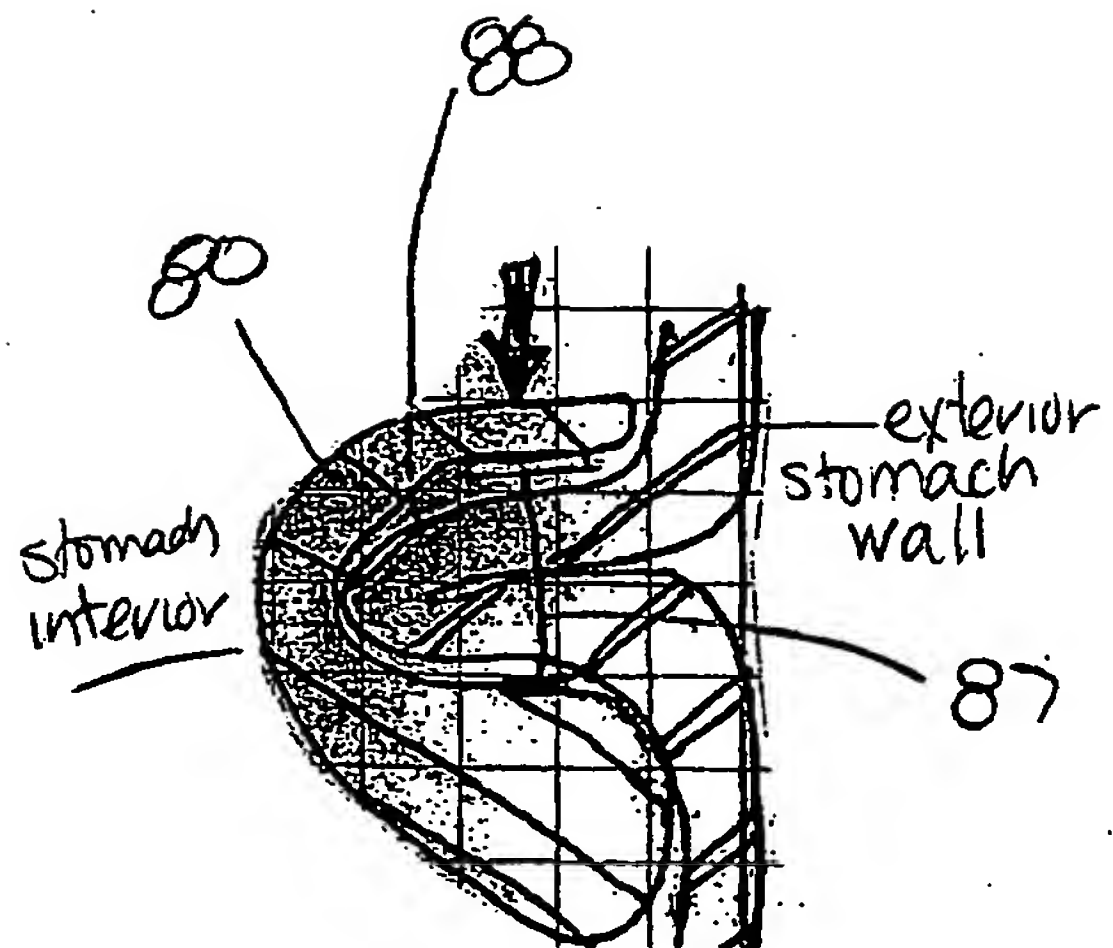
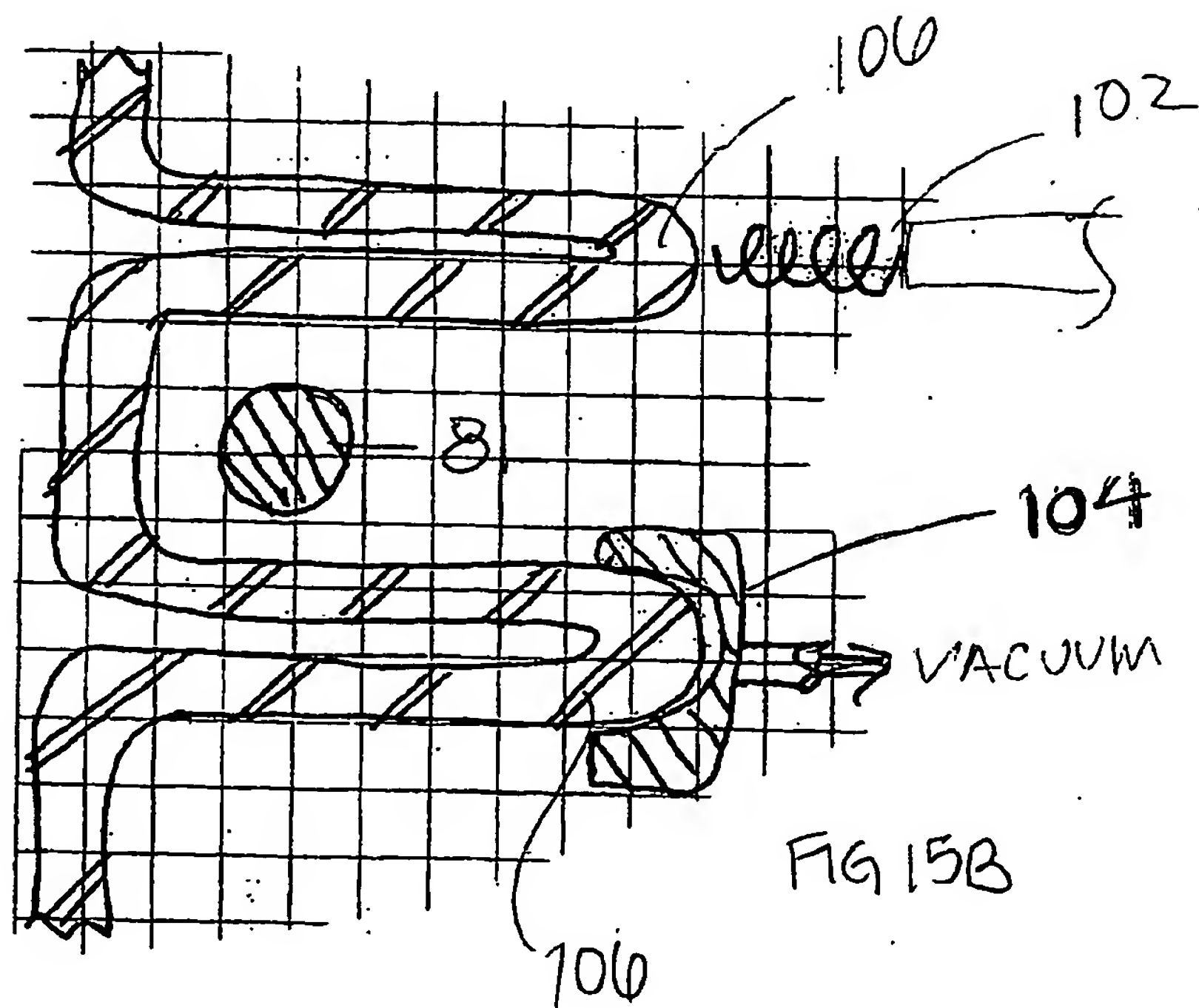
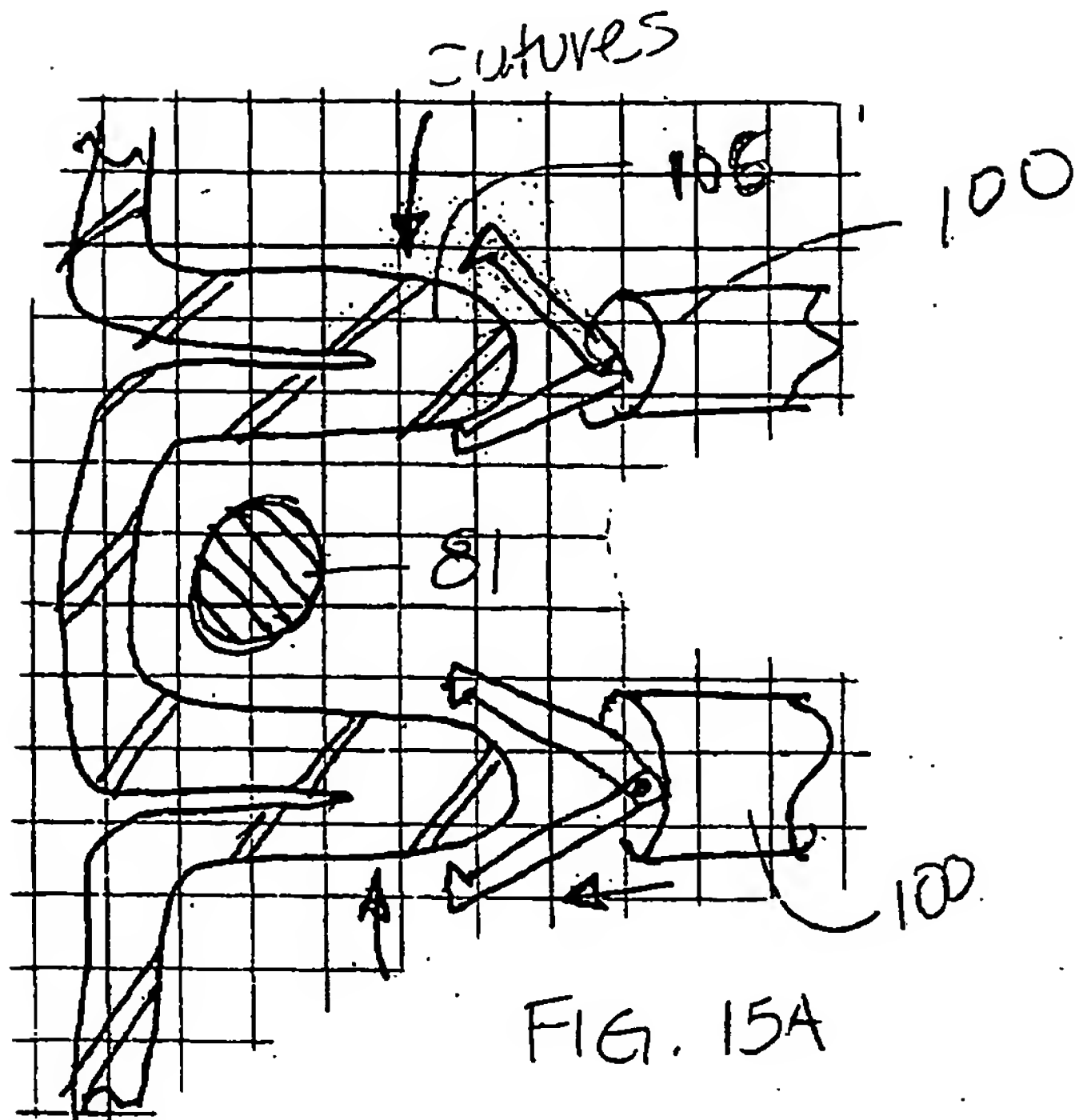


FIG 14B



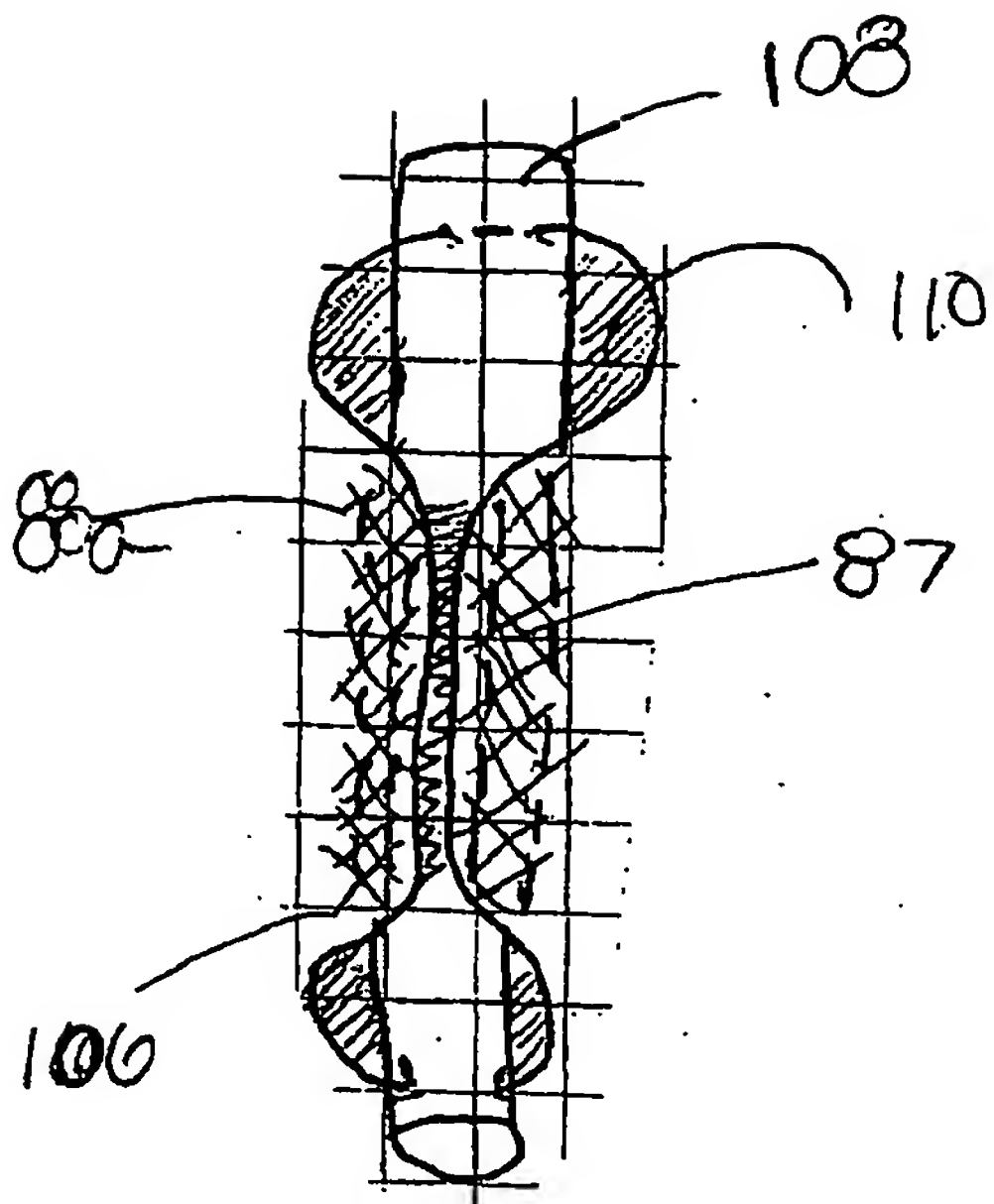


FIG. 16A

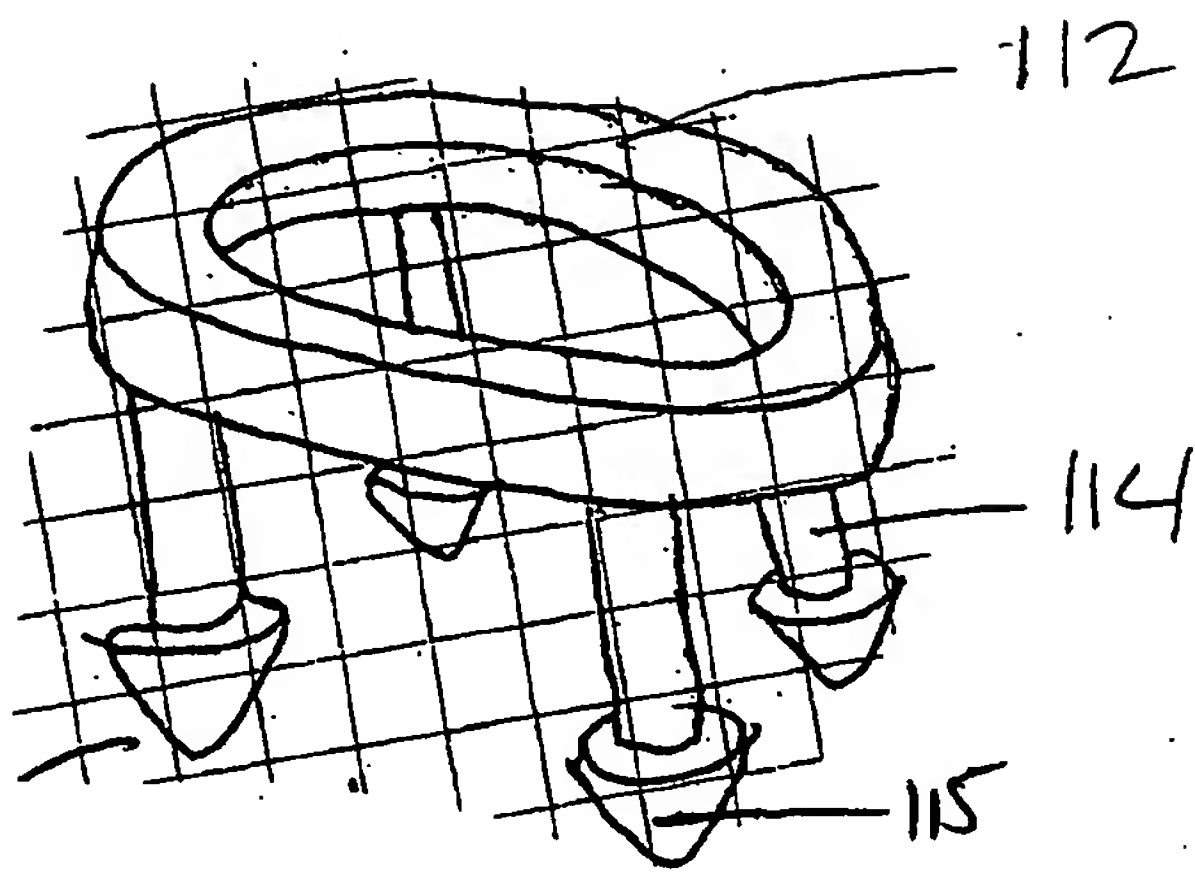


FIG. 16B

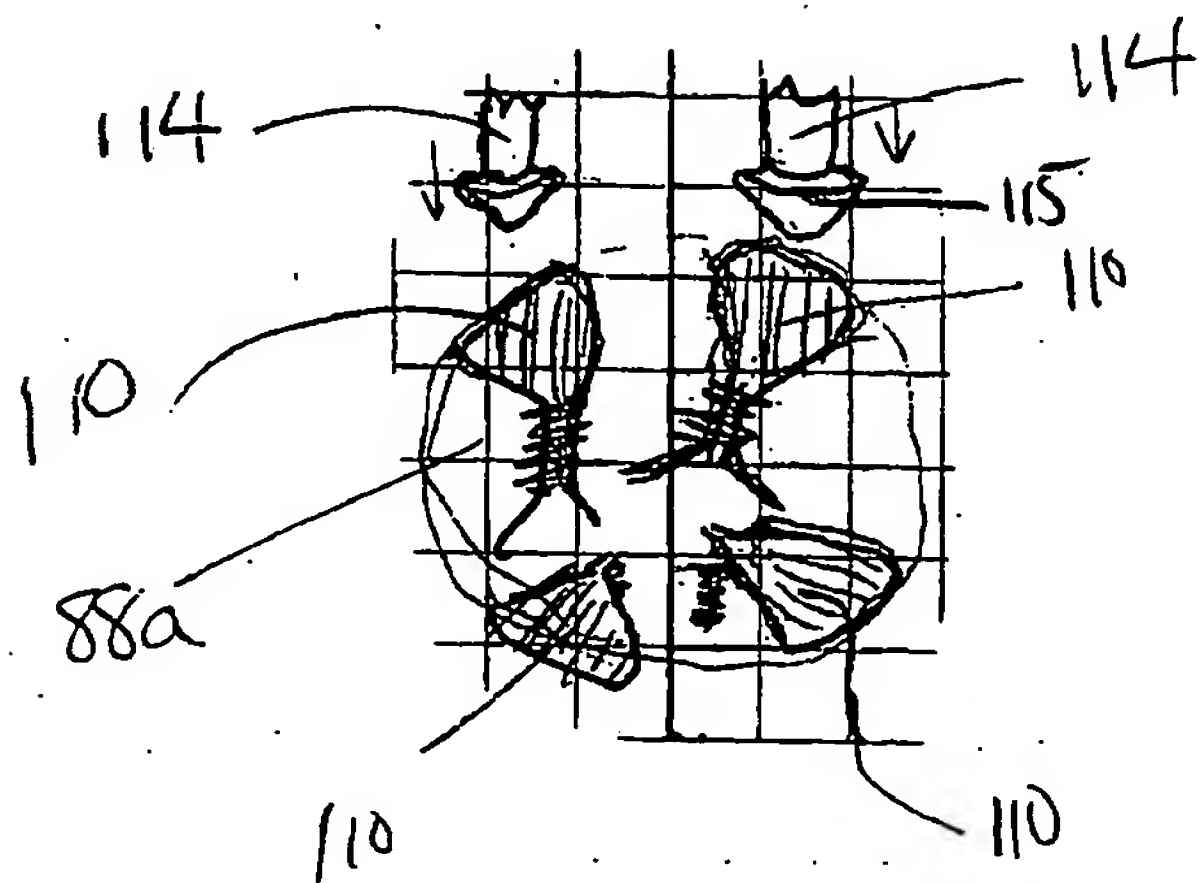
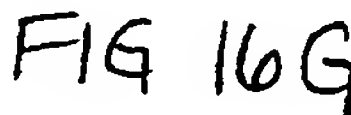
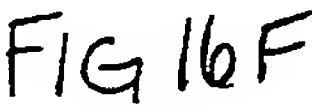
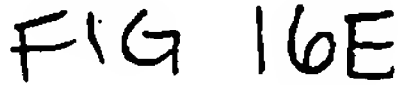


FIG. 16C



Stomach
interior

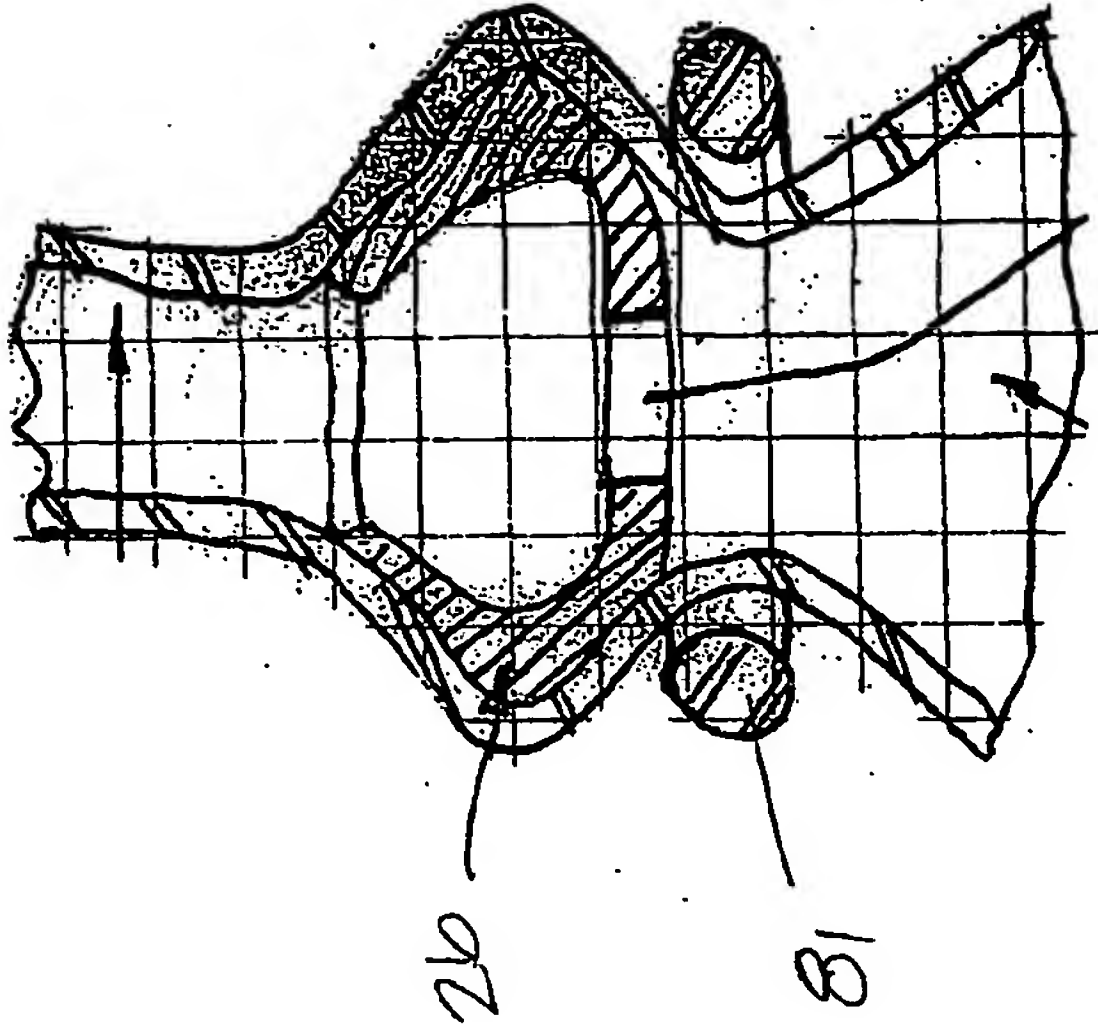


FIG. 17B

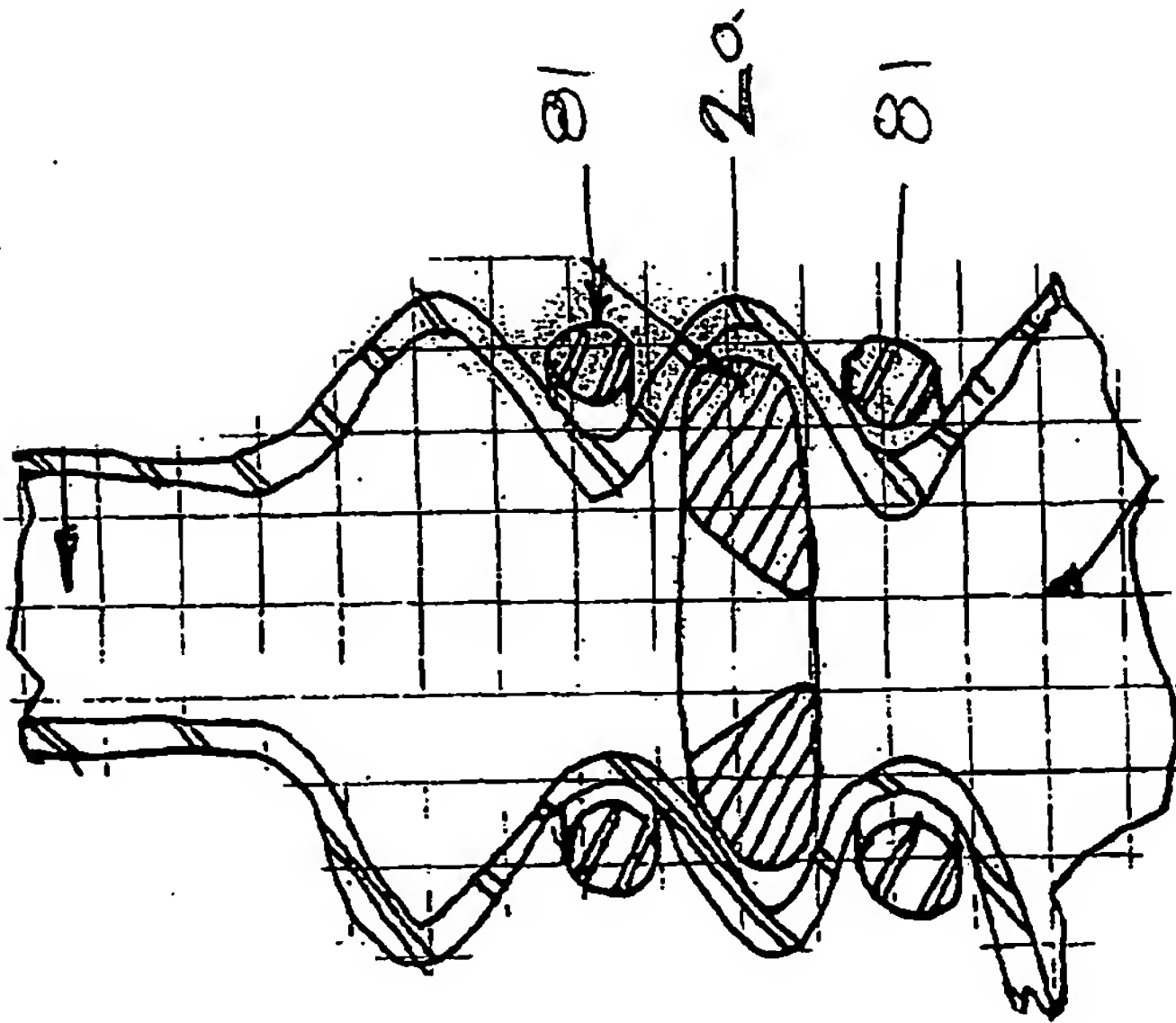


FIG. 17A

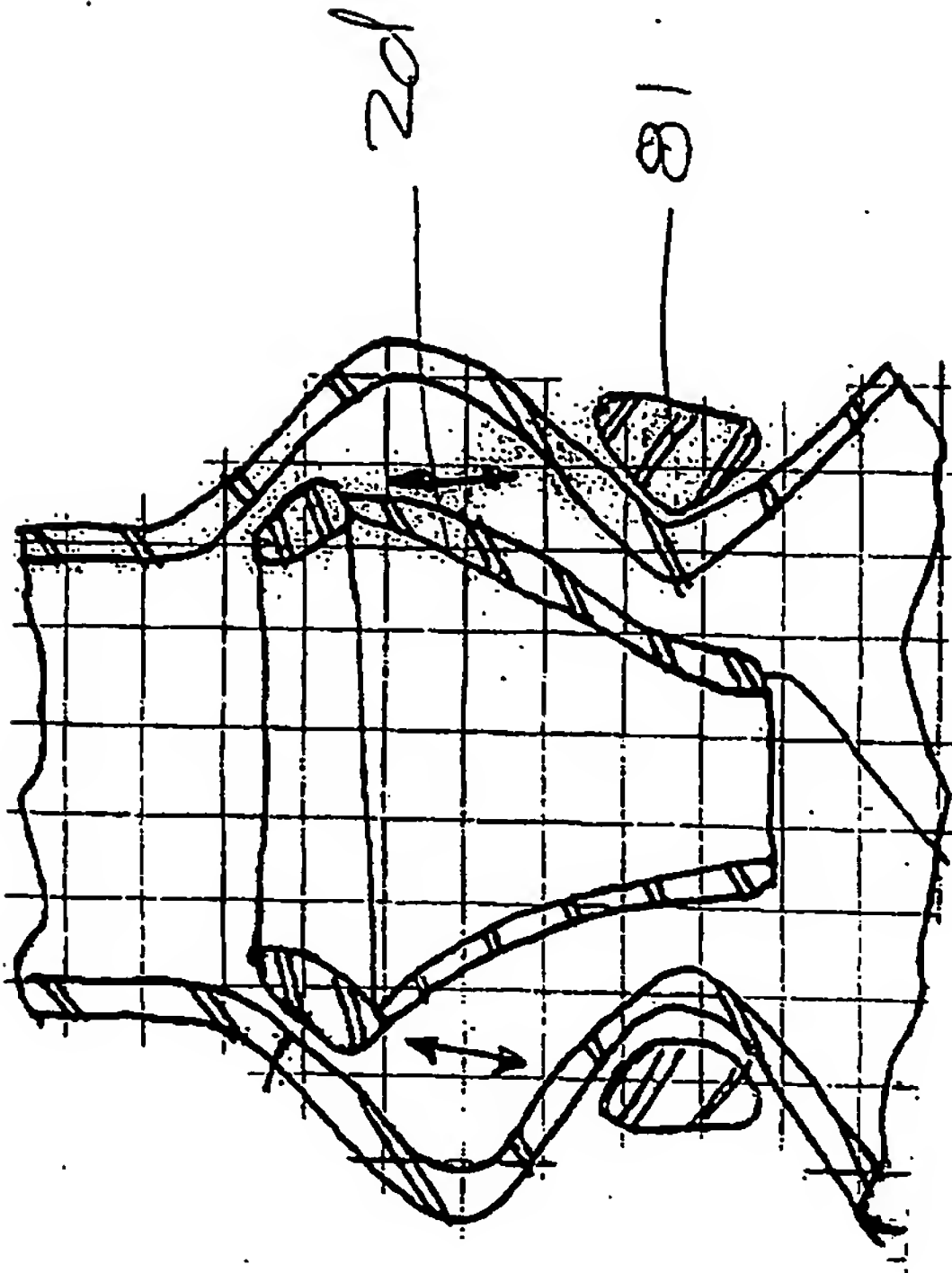


FIG 19

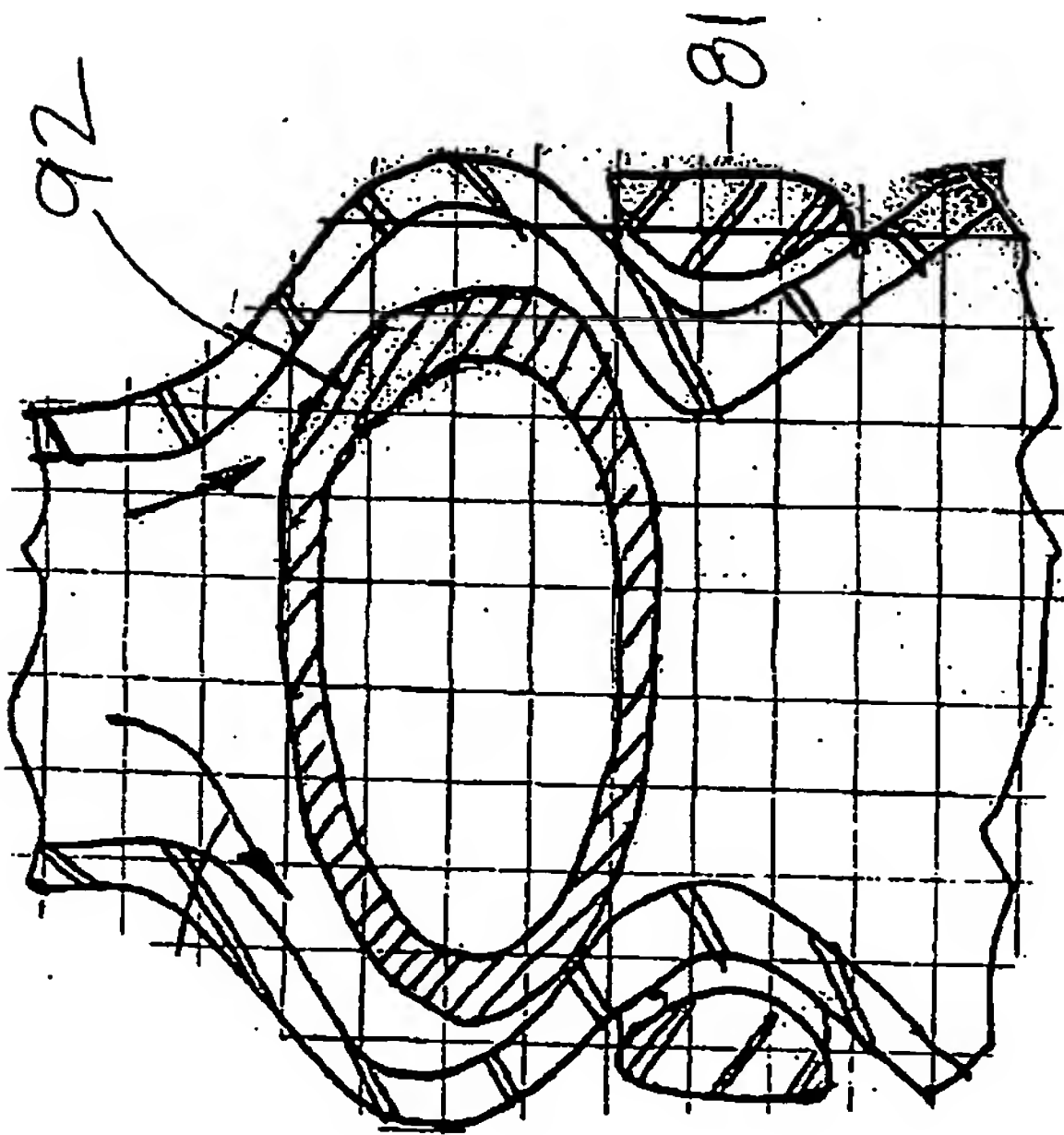
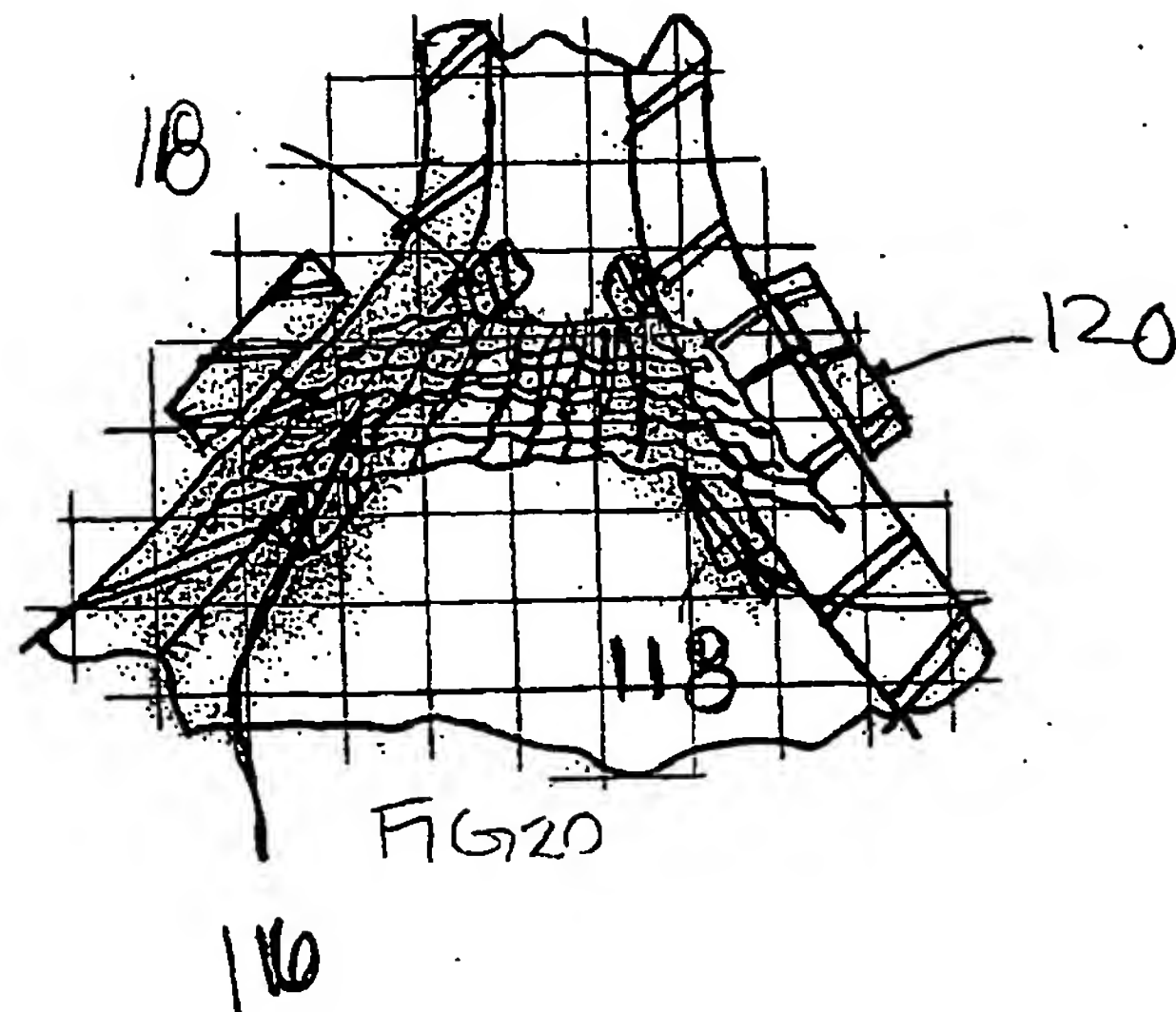


FIG 18



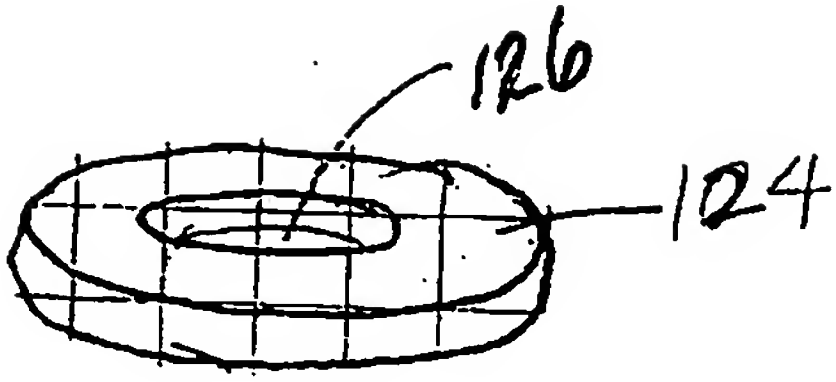


FIG 21A

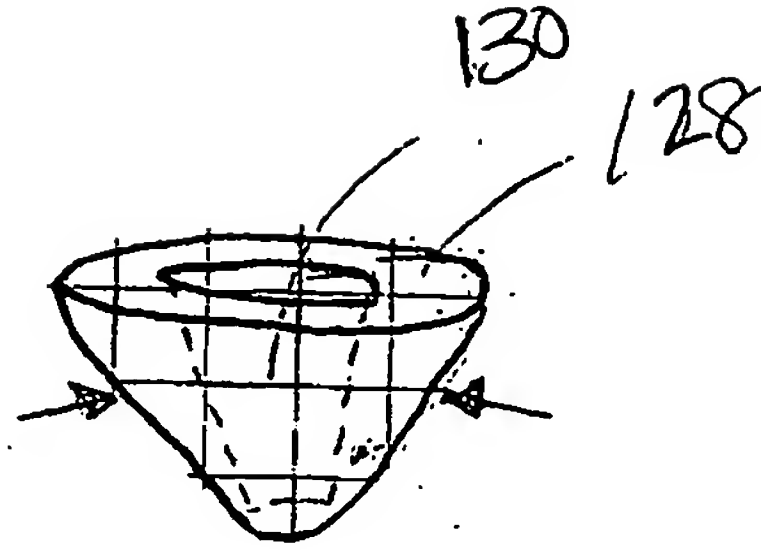


FIG 21B

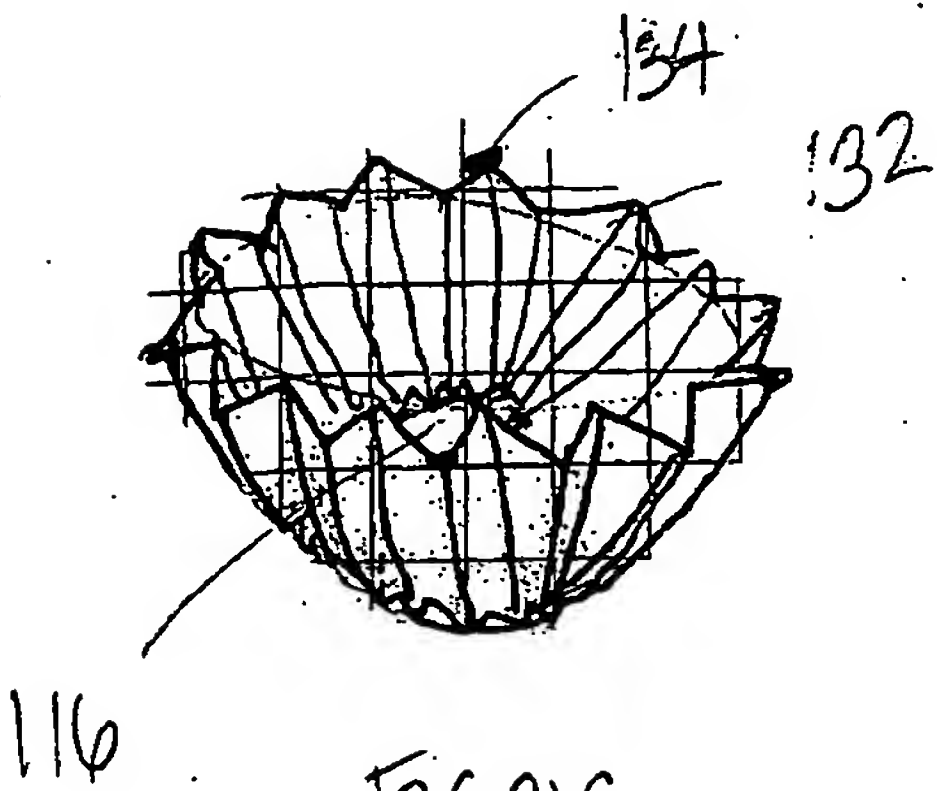


FIG 21C

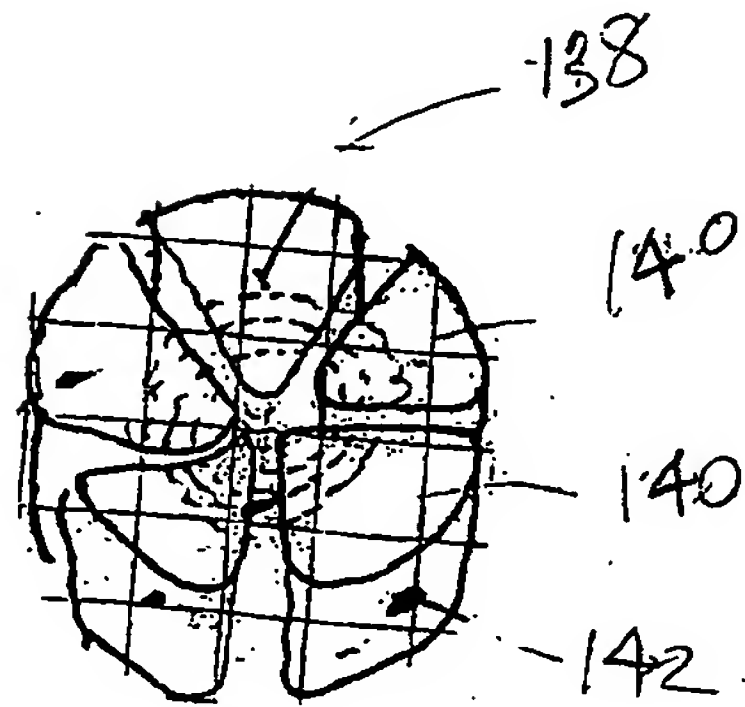


FIG 21D

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